



Henlius (2696.HK) 1H21 Results Investor Presentation

August 2021

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Company Overviewand Strategy



Company Mission & Key Milestones

Mission: Affordable Innovation, Reliable Quality Products Commercially Launched Domestically / 3/1 Internationally **Products under NDA Review Phase III Trials** 5 **Commercial Capacity This** 20,000L Year / Next Year /44,000L

2021.04	HLX10 (PD-1 mAb, serplulimab) NDA Accepted by NMPA and Proposed to be Granted Priority Review
2020.12	HLX01 (rituximab) for Rheumatoid Arthritis indication 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
2019.02	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
Executive Director
CEO & President

- 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









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





Jean-Michel Gries
President of Hengenix Biotech
Joined in Aug. 2021





Wenfeng Xu Senior Vice President of Research and Development

Genentech
A Member of the Roche Group





Ningshu Liu Senior Vice President Joined Henlius in Aug. 2020





Xinlei Li Chief Financial Officer Joined Henlius in Dec. 2020

FOSUN PHARMA 复星医药



Ping Cao
Head of Business Development





Bristol-Myers Squibb



Kurt Yu Head of Marketing and Commercial Operation Joined Henlius in Aug. 2019







Wallis Zeng Head of Sales Joined Henlius in Sep. 2019

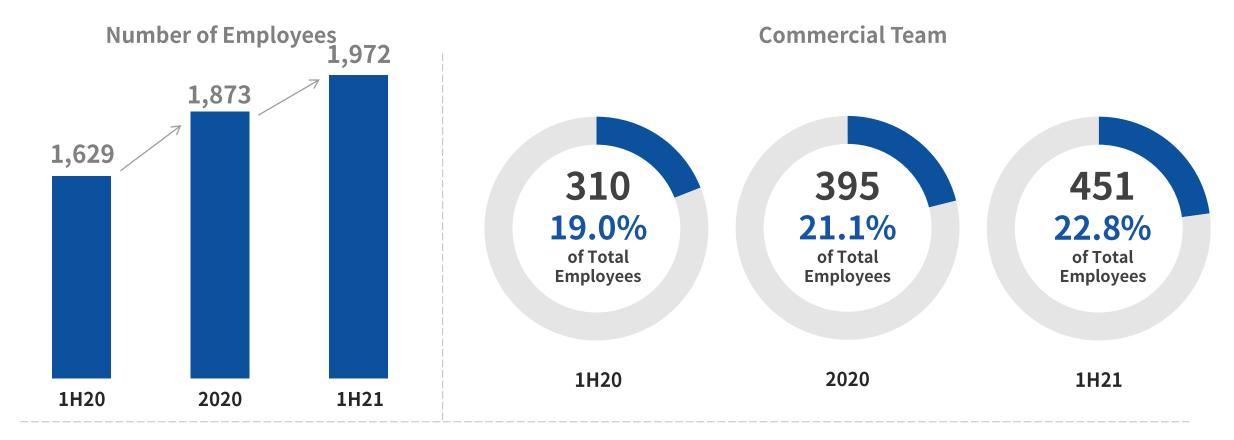








Company Size: the Number of Employees Rapidly Grew with Commercial Team Expanding Quickly



R&D	Clinical	Manufacturing	Quality	Commercial	Administrative
305	259	544	241	451	172



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

Strategic Goals

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

Commercialization

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

While maximizing biosimilar

centers, strengthen translational medicine capability, advance differentiated innovation

Under the premise of guaranteeing "Henlius Quality", further improve manufacturing capability. optimize manufacturing technology, create competitive economies of scale

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

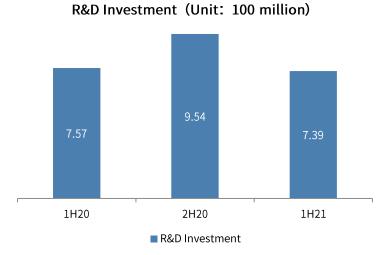


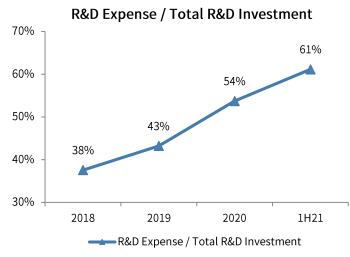
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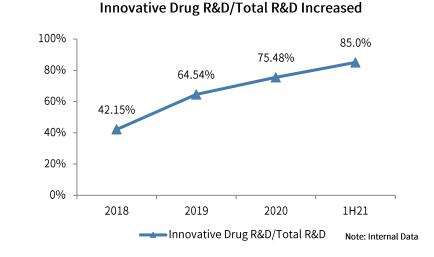
1H21 Review: Products and Pipeline



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







3 NDAs under Review

- HLX10 (PD-1, serplulimab) for the treatment of MSI-H has been granted priority review
- 汉利康® (HLX01, rituximab) rheumatoid arthritis
- 汉贝泰[®] (HLX04, bevacizumab)

Progress of international multi-center clinical research projects

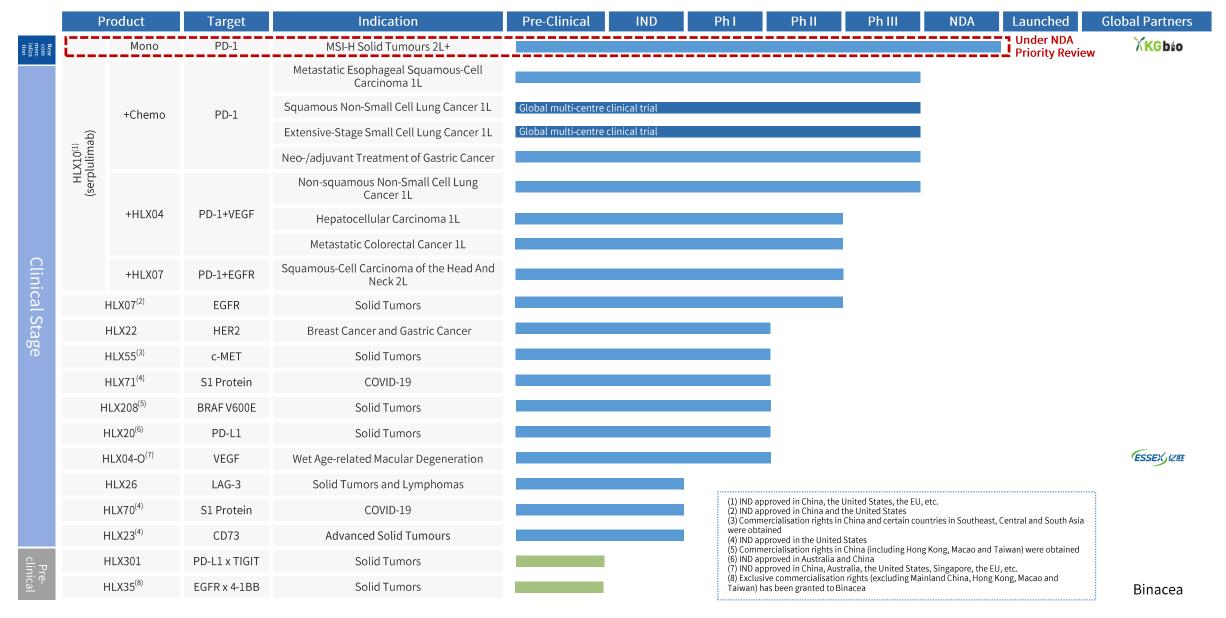
- IND applications of HLX04-O (VEGF) for wAMD have been approved in Australia, the USA, and Latvia
- First subject dosed of HLX71 (ACE2-Fc receptor fusion protein) for the treatment of COVID-19 in the USA

Progress of domestic clinical research projects

- Enrollment of subject was completed for combo of HLX10 (PD-1) + HLX04 (VEGF) for the treatment of advanced hepatocellular carcinoma (HCC)
- First subject dosed in a phase II/III clinical trial for combo of HLX10 (PD-1)+HLX04 (VEGF) for the treatment of mCRC
- First subject dosed in a phase 1 clinical study for HLX04-O (VEGF) for the treatment of wAMD
- IND application of HLX15 (daratumumab) for the treatment of multiple myeloma has been approved by the NMPA
- IND application of HLX26 (LAG-3) for the treatment of solid tumors and lymphomas has been approved by the NMPA
- IND application of HLX23 (CD73) for the treatment of advanced solid tumors has been approved by FDA



Bio-Innovative: In-house Integrated R&D platform Covering Multiple Innovative Targets



Focus on Lung and GI Cancer: PD-1 as the Opportunity and Foundation

		Product	Target	Indication	Pre-clinical II	ND	Ph I	Ph II	Ph III	NDA	Launched
	Lur	HLX10+Chemo	PD-1	Squamous Non-Small Cell Lung Cancer 1L		Global multi-centre clinical trial					
	Lung Cancer	HLX10+Chemo	PD-1	Extensive-Stage Small Cell Lung Cancer 1L		Global mu	lti-centre cli	nical trial			
	ביר	HLX10+04	PD-1+VEGF	Non-squamous Non-Small Cell Lung Cancer 1L							
	Gas	HLX10	PD-1	MSI-H Solid Tumours 2L+							
Calice	Gastrointestinal Cancer	HLX10+Chemo	PD-1	Neo-/adjuvant Treatment of Gastric Cancer							
	tinal	HLX10+04	PD-1+VEGF	Metastatic Colorectal Cancer 1L							



PD-1+Bio-Innovative: Lung Cancer TA well covered

1st Line Treatment

2nd Line + Treatment Potential Products

HLX20 (PD-L1) Phase I

sq-NS

Lung

Cancer

HLX04 (bevacizumab, VEGF) NDA HLX10+HLX04 (PD-1+ VEGF) Phase III

HLX10+Chemp (PD-1+ Chemo) Phase III

HLX13 (ipilimumab, CTLA

4) IND HLX208 (BRAF Inhibitor) Phase I

HLX12 (ramucirumab, VEGFR2) Phase I

HLX26 (LAG-3) Phase I

HLX23 (CD73) Phase I

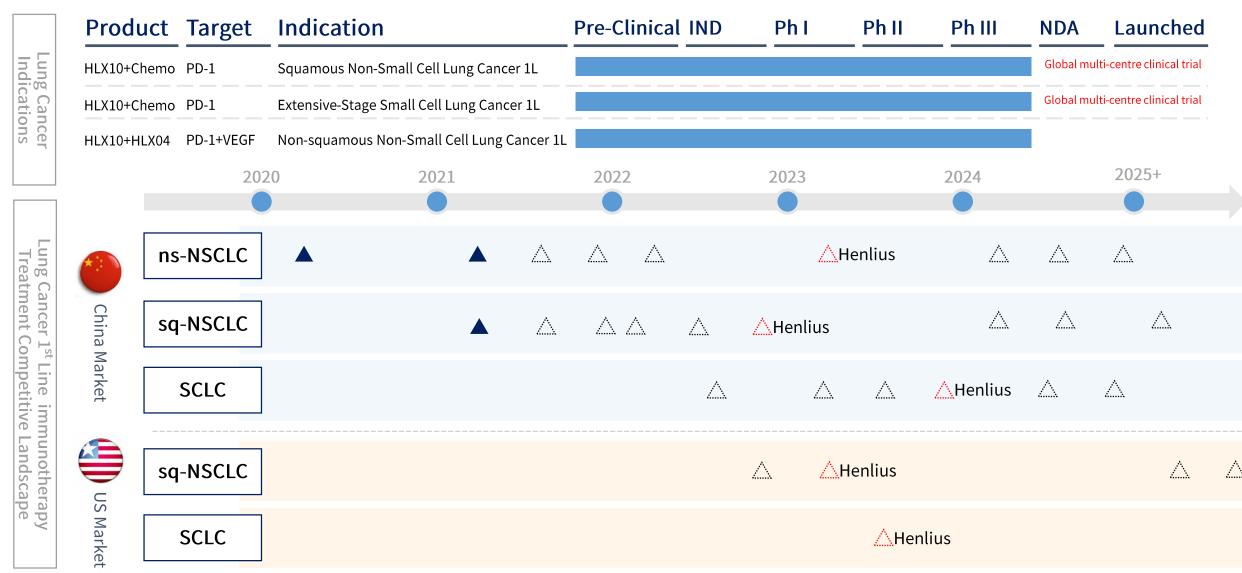
HLX301 (PD-L1 x TIGIT) Pre clinical

HLX35 (EGFR x 4-1BB) Pre clinical

HLX10+Chemo (PD-1+ Chemo) Phase III



Serplulimab (PD-1): Competitive Domestically & Internationally



Effective Combination of Innovative and Mature Products to Solve the Unmet Needs of Gastrointestinal Caner

Neo-/adjuvant 1st Line Treatment 2nd Line + Treatment HLX02 (trastuzumab, HER2) Marketed HLX10+Chemo (PD-1+ Gastric HER2+ Chemo) Phase II HLX22+02 (HER2 + HER2) Phase I MSI-H HLX10 (PD-1) NDA Cancer HLX12 (ramucirumab, VEGFR2) Phase I Others Colorectal HLX10 (PD-1) NDA MSI-H HLX13 (ipilimumab, CTLA-4) IND HLX05 (cetuximab, EGFR) KRAS+ Phase I HLX12 Cancer HLX04 (bevacizumab, VEGF) NDA (ramucirumab, VEGFR2) Phase I **HLX208 (BRAF Inhibitor) BRAF+** Phase II (In Plan)



Actively Promote HLX208 (BRAF V600E Inhibitor) Clinical Trials and Accelerate the Launch

Strategic Significance

Key Clinical Trials

Planned

- "Fast-to-market" project
- HLX208 is expected to be the second BRAF inhibitor in Lung Cancer launched in China
- "Fast-to-market" project
- HLX208 is expected to be the only approved BRAF inhibitor (LCH&ECD) in the medium to long term
- Major indication development after understanding the efficacy of the drug, quickly launch the 1st line Ph III trial.
- HLX208 is a tier 1 product in this indication
- HLX208 is expected to be the only approved BRAF inhibitor (ATC)
- Exploring potential indications

Non-Small Cell Lung Cancer

 Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester Disease (ECD)

 Metastatic Colorectal Cancer (mCRC, Mono and Combo)

Anaplastic Thyroid Cancer (ATC)

- Melanoma (Mel)
- Brain Tumor (BT)
- Other Solid Tumor

Ph 2

Ph 2

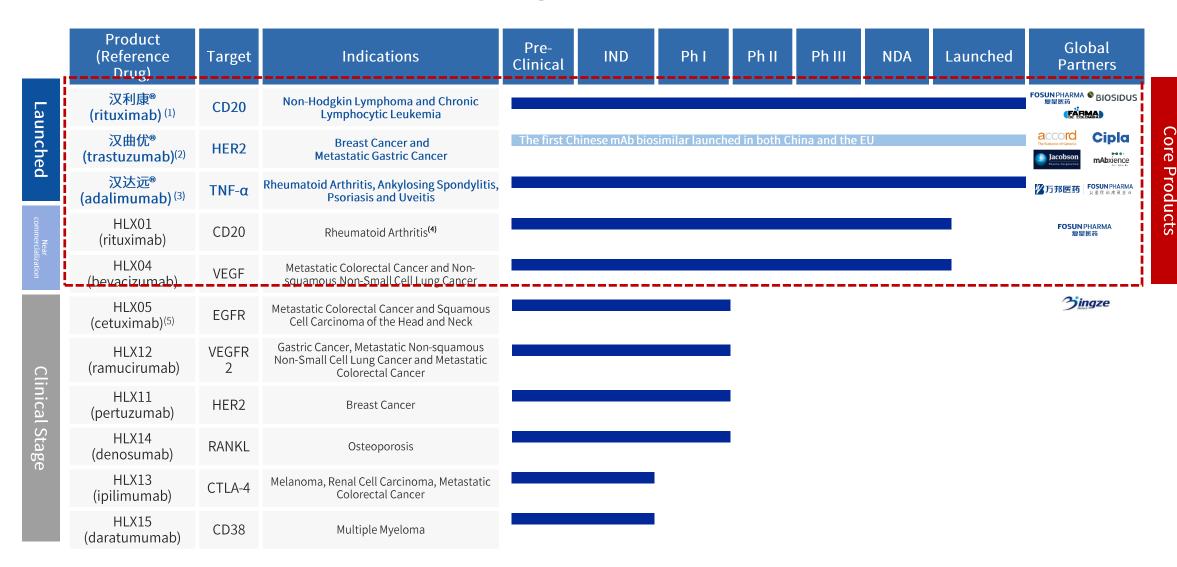
Ph 2

Ph 1b/2

Ph 1b/2



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



⁽¹⁾ Approved by the NMPA in February 2019, being the first domestic biosimilar



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⁾ Considered as biologic medicine since the reference product has not yet been approved for the relevant indications

⁽⁵⁾ Commercialisation rights in China have been granted to Shanghai Jingze

Biosimilar: Multiple Blockbuster Drugs Have Competitive Advantages in China

	汉利康® (rituximab)		汉曲优® (trastuzumab)		汉达远 [®] (adalimumab)		汉贝泰® (bevacizumab)
	Product positioning: become a leader in China's rituximab market First-mover advantage – First biosimilar in China, first domestic rituximab, 20 months earlier than No.2		Product positioning: become a leader in China's trastuzumab market First-mover advantage – First domestic trastuzumab, launched nearly 2 years earlier than peers		Product positioning: become a leader in China's adalimumab market Pricing advantage – Current lowest price, greatly improve patient affordability First domestic adalimumab to		Product positioning: become a strong competitor in China's bevacizumab market Differentiated clinical data – 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) Strong sales team – Fosun Pharma built dedicated sales team with about 400 people	•	First self-developed domestic China and EU approved antibody drug Strong sales team – self-built team with 450 people	•	have phase 3 clinical data on psoriasis; sNDA for uveitis has been approved (2021.04) Strong sales team – Fosun Pharma had a team with nearly 1,000 people in rheumatology department	•	Huge Combo potential – Combo with HLX10 (PD-1) for ns-NSCLC, HCC, etc. Fully utilize differentiated 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 Accord Essex (1061.HK) **Exclusive licensing and commercial** Exclusive commercial rights of trastuzumab Co-development and exclusive license rights of rituximab (HLX01) in (HLX02) in over 70 countries and regions in agreement with Essex for Colombia, Peru, Ecuador and bevacizumab (HLX04) in eye disease Europe, MENA, CIS, USA & Canada Venezuela indications globally **ESSEX**) 1Z胜 **FOSUN PHARMA Iacobson** FARMA **mAb**xience Cipla Mabxience **Cipla** Jacobson (2633.HK) Exclusive commercial rights of Exclusive commercial rights of HLX02 in **Exclusive commercial rights of** HLX02 in Argentina, Uruguay, and Australia, New Zealand, Colombia and trastuzumab (HLX02) in Hong Kong Paraguay Malaysia and Macau



Efficiently Promote IND Application of Pre-clinical Products

- Recognize the value of pre-clinical pipeline and accelerate the submission of IND applications for CD38, LAG-3, CD73 targets products domestically and globally.
- IND application of two bispecific products is expected to be submitted in the second half of 2021.

Product (Reference Drug)	Target	Indications	1Q21	2Q21	3Q21	4Q21
HLX15 (daratumumab)	CD38	Multiple Myeloma	2021/1 IND Ap	oplication Approved b	y NMPA	
HLX26	LAG-3	Solid Tumors and Lymphomas		2021/4 IND A	pplication Approved b	oy NMPA
HLX23	CD73	Advanced Solid Tumours		202	1/5 IND Application Ap	pproved by FDA
HLX301	TIGIT x PD-L1	Solid Tumours	Expected to Subm	it IND Application in t	he Second Half of 202	1
HLX35	4-1BB x EGFR	Solid Tumours	Expected t	o Submit IND Applica	tion in the Second Ha	If of 2021



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1H21 Review: Manufacturing



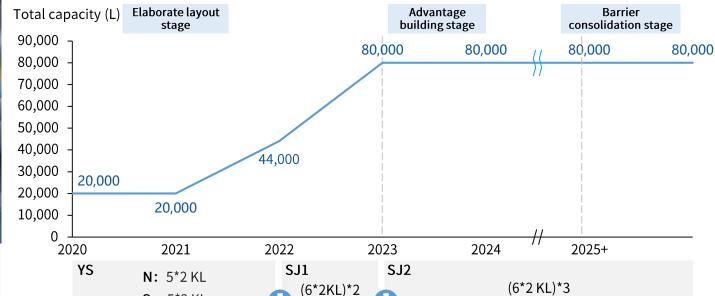
Integrated Platform Advantage: Three Manufacturing Bases Will Further Increase Integrated Platform Advantage

Manufacturing platform for commercial production with cost advantage

- Continue to expand commercial manufacturing bases: Xuhui Facility Songjiang First Plant Songjiang Second Plant
- 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)

S: 5*2 KL

- 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)

- 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+)

- Continue to optimize process, build industry-wise quality/costleading production line
- Assist government improve biologics manufacturing standards, establish made-in-China quality benchmark

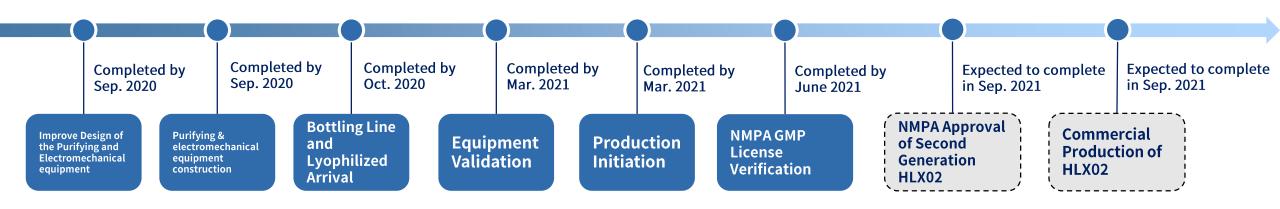


Songjiang First Plant: the construction of pilot conventional workshop and continuous flow workshop have been completed

The continuous flow workshop construction has been completed and the continuous flow pilot production plan has been initiated for the Songjiang First Plant.

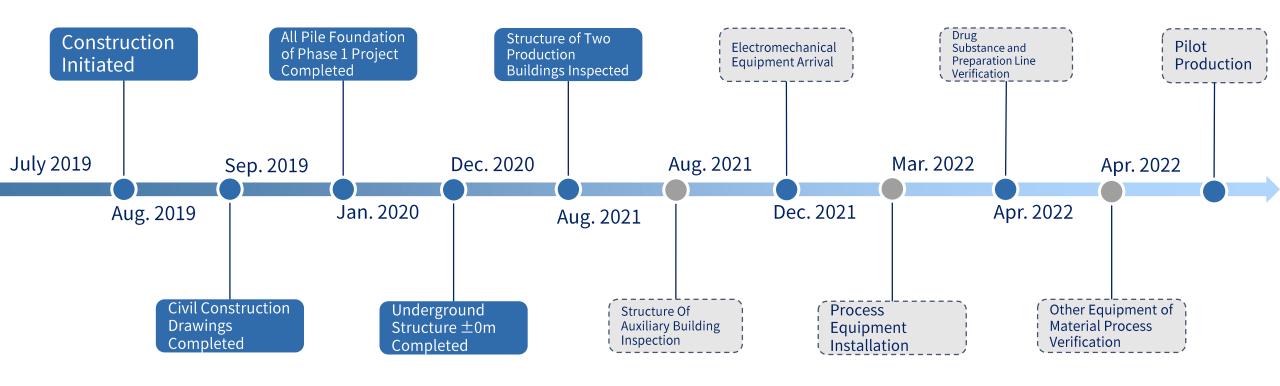


The validation and production of HLX02 using the second-generation process have been completed as the first project in Songjiang First Plant.





Songjiang Second Plant: the project construction is progressing smoothly



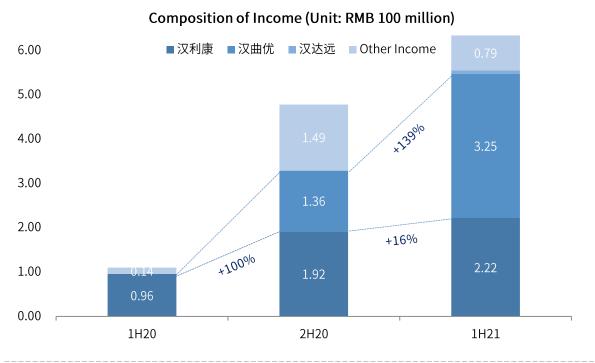


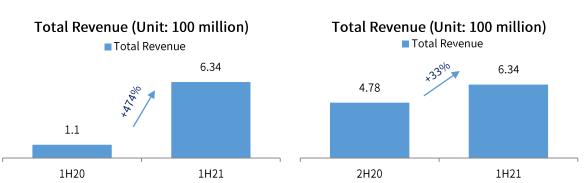
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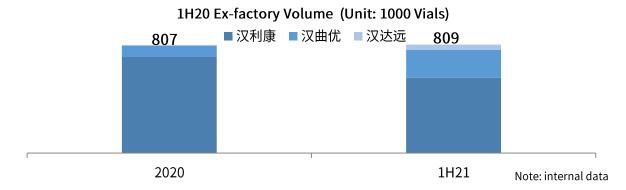
1H21 Review: Commercial Operation

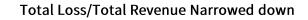


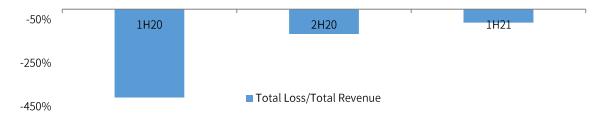
1H21 Sales: lead by 汉曲优® and 汉利康®, the sales volume continues to increase











- Rapid growth of total revenue: as of June 30, 2021, the company's revenue was approximately RMB 634 million, an increase of about RMB 155 million from the second half of 2020 and an increase of RMB 45 million from 2020, mainly due to the increase in sales resulting from the commercialization of core products
- Core product sales continue to increase: in the first half of 2021, the ex-factory volume of three launched products had exceeded that of 2020. Sales of 汉曲优 was outstanding with a revenue accounted for more than half of the total revenue
- Loss rate decrease significantly: the loss of 1H21 was about RMB 394 million, a decrease of about RMB 152 million from the second half of 2020 which mainly due to the revenue of core products and the decrease of the expense ratios



汉曲优® (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 Channel Marketing

- 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



汉曲优[®] (trastuzumab): Accelerate Admission to Hospital, Continue to Increase Volume

Market Access Continues to Advance

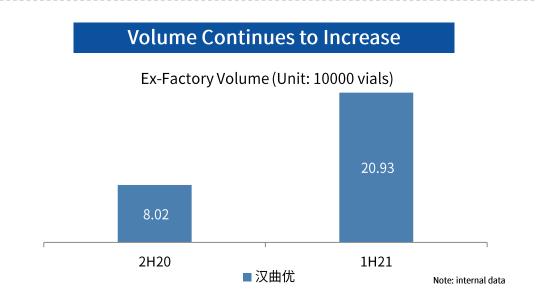
- Domestic market: completed bidding in all provinces and municipalities in mainland China and inclusion into the medical insurance procurement platform of all provinces and municipalities. 45% of the Top 1000 hospitals had admitted the drug
- Global Market: marketed in nearly 20 EU countries and regions. Zercepac® (150mg) had successfully entered a number of top hospitals in the UK

Obvious Price Advantage

- Reference drug Herceptin®: RMB 5,500/440mg; 汉曲优®: RMB 1,688/150mg
- 10% off of the reference drug based on price per milliliter
- The **60mg** specification is expected to be approved in 2021. The combination of these specifications could meet different needs of the patients

Commercial Team Continues to Build up

- A commercialization team with about 450 people at the end of the Reporting Period, including a sales team composed of more than 360 professionals.
 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, nearly 20,000 HER2+ patients have been treated. Compared with the following trastuzumab, the target doctor group has more experience





汉利康[®] (rituximab): Continue to Increase Volume and Have a Solid Market Position

Market Access Continues to Advance

- 30 provinces and municipalities had approved the inclusion of 100mg into the medical insurance procurement platform
- 28 provinces and municipalities had completed official platform/filed procurement
- Over 70% of the core hospitals had admitted the drug

Obvious Price Advantage

- Reference Drug MabThera®: RMB 2,418/ 100mg
- 汉利康®: RMB 1,398/100mg
- 40% off of the price of the reference drug, obvious advantages
- The price of 500mg will be more competitive

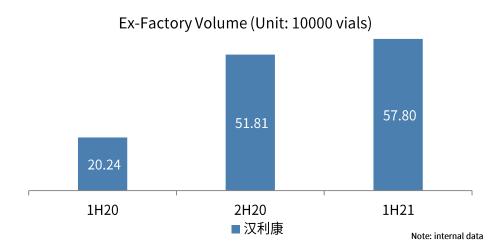




Add 500mg Specification

- The launch and supply of 500mg commenced in May 2021 and the official platform/filed procurement of the product was completed in 4 provinces and municipalities in mainland China as of June 2021
- The different specifications of 汉利康 not only provide a convenient choice for the patients, but also pave the way for the increase in sales in future

Volume Continues to Increase





汉达远®(adalimumab): Give Every Auto-immune Disease Patient Proper and Possible Treatment

Market Access Continues to Advance

- Successfully included into the medical insurance procurement platform for **27** provinces and Municipalities
- Jiangsu Wanbang will be responsible for the domestic commercial sales. Wanbang has a sizeable Department of Rheumatology and Immunization and a mixed-line sales team serving the broad market. The marketing team has a high level of professional communication skills and medical knowledge, and boasts successful experience in the commercialization of the rheumatoid treatment product Yolitong® (Febuxostat Tablet).

Obvious Price Advantage

- Reference drug Humira®: RMB 1290/40mg;汉达远®: RMB 899/40mg
- 30% off of the price of reference drug and lower than that of the competitors

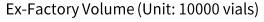


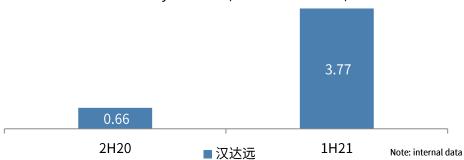
Differentiations of the Indications

- The first domestic adalimumab with Phase III clinical evidence of psoriasis
- In January 2021, the supplemental new drug application for the new indication of **uveitis** was accepted by the NMPA, and such supplemental new drug applications were approved in April 2021

Expect to Access the Market Quickly

 Expected to increase the volume quickly based on the competitive advantages of Jiangsu Wangbang







Serplulimab (PD-1) and Bevacizumab: Commercial Strategy

Serplulimab (PD-1) – 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					
 Accelerate expansion of PD-1 indication Actively advance PD-1 combo therapy PD-1 + innovative therapy Combo 	 Differentiated competition, rapidly increase market share Rapid access Strategic partnership, empower pan-tumor ecosystem 	 Make data-wise preparation for entering major markets through global multi-center clinical study Achieve overseas market development through global partnership including registration, access, commercialization 					

	Bevacizumab – 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	 Centralize best resources for rapid market access in mass market 	 Actively explore combo therapy with our own products through real-world data or 					
•	Enhance platform collaboration with mass market	 Meanwhile fully prepare for VBP and turn threat into opportunity 	clinical studies initiated by researchers					
•	Rapid deployment for more market share	tineat into opportunity						



3 Outlook



Outlook for the second half of 2021

Capitalize on first-entrant advantages and increase the global market coverage of products, continue to commercialize more products

- HLX02汉曲优[®]: consolidate the construction of the diagnosis and treatment ecosystem for HER2-positive patients. The sales team is expected to further expand and reach approximately 390 cities across the country, covering nearly 4,500 DTP pharmacies/hospitals
- HLX01汉利康®: continue to strengthen sales and focus on the growth of hematology oncology field; focus on promoting the 500mg/50ml medical insurance network and hospital admission in all provinces across the country
- HLX03汉达远®: expect to cover 4,000 specialists and 5,000+ DTP pharmacies/hospitals this year
- HLX04 (bevacizumab): expected to be approved in the fourth quarter of 2021; plans to start the sNDA of glioma (GBM) after the launch of
- HLX01 (rituximab) rheumatoid arthritis (RA): expected to be approved be approved by the end of 2021 or in the first half of 2022; prepare for commercialization
- HLX10 (PD-1): the business cooperation with KG Bio will be further carried out following the approval of the product; expect to submit the NDA of indication of
 combining chemotherapy in first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer in mainland China in the second half of 2021

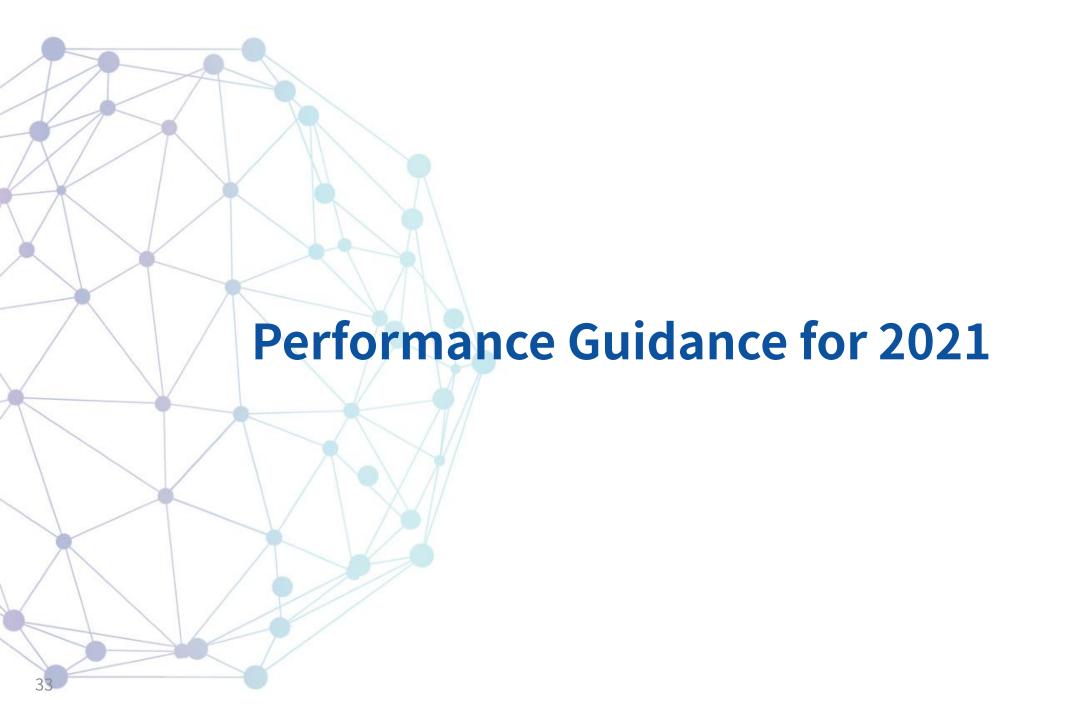
Rapidly build diversified clinical-stage innovative pipeline through internal R&D and license-in

- Continue to optimize and accelerate the R&D pipeline development; utilize the decision-making mechanism and working pattern and significantly improve the efficiency of R&D
- HLX10 (PD-1) based clinical trials of I/O 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 Facility: maximizing production capacity while guaranteeing "Henlius Quality"; further promote lean operations and continue to decrease the manufacturing cost; planned to add a prefilled syringe production line this year
- Songjiang First Plant: ready to accept the NMPA GMP Compliance On-Site Inspection; plan to submit the sNDA of 2nd generation manufacturing process of汉曲优®
- Songjiang Second Plant: promote the construction and operation







Reliable Quality | **Affordable** Innovation

