



## 2020 Corporate Social Responsibility Report

Shanghai Henlius Biotech, Inc.

# Reliable Quality Affordable Innovation

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## **ABOUT THIS REPORT**

This is the second Corporate Social Responsibility ("CSR") report published by Shanghai Henlius Biotech, Inc. ("Henlius", "We" or "the Company"). The purpose of this report is to provide stakeholders with an objective and accurate account of the Company's strategies, policies, measures and achievements in sustainable development, with a focus on Environmental, Social and Governance ("ESG") and social responsibility.

Period of Reporting	The reporting period covers the information and data of the Company from 1 January 2020 to 31 December 2020 (the "reporting period" or the "current year"), with some information relating to 2019 and the first and second quarters of 2021.			
Scope of Reporting	The disclosure scope of this report covers Shanghai Henlius Biotech Inc. (stock code 2696. HK) and its subsidiaries, which is consistent with that of the 2020 Annual Report of the Company.			
Basis and Reference	The report is compiled as required by the <i>Environmental</i> , <i>Social and Governance (ESG)</i> <i>Reporting Guide</i> , Appendix 27 of <i>Rules Governing the Listing of Securities on the Stock</i> <i>Exchange of Hong Kong Limited</i> . It also drew reference from the <i>Consultation Conclusions</i> <i>on Review of the Environmental</i> , <i>Social and Governance Reporting Guide and Related Listing</i> <i>Rules</i> released by The Stock Exchange of Hong Kong Limited in December 2019. The compilation of the report follows and keeps alignment with the GRI Standards published in 2016.			
Information Sources of Report and Reliability Reassurance	The information and examples in this report are mainly from company statistical reports and relevant documents. The Company warrants that this report is free from any false records or misleading statements, and is held responsible for the truthfulness, accuracy and completeness of the content of the report.			
Receive and Respond to This Report	The report is published in Simplified Chinese, Traditional Chinese and English. In the event of any discrepancy between the Chinese and English versions, the Simplified Chinese version shall prevail. For environmental protection, we recommend reading the electronic version of the report, which is available on the Company's website (www.henlius.com). We value the opinions of different stakeholders and welcome readers to contact us via the contact details below. Your comments will help us further improve this report and our overall Corporate Social Responsibility performance.			
Contact Details	Email: PR@henlius.com Address: 9/F, Innov Tower, Zone A, No. 1801 Hongmei Road, Xuhui District, Shanghai			

## **MANAGEMENT MESSAGE**



Qiyu Chen Chairman and Non-executive Director



Wenjie Zhang Executive Director, Chief Executive Officer, President The year 2020 marks the 10th year since Henlius' establishment. For the past 10 years, we have been gradually taking on a more important and high-level mission, with "Reliable Quality, Affordable Innovation" as our initial goal. While developing the business, we have never forgotten the need to grow into a socially responsible company. We persist in doing the right things, the hard things and the things that take time to build up, thus bringing high quality, affordable biologic drugs to more patients in need.

With this mission in mind, we have made great efforts on all fronts.

We respond positively to the requirements from the regulatory authorities by embedding the concept of corporate social responsibility in all aspects of our operations. Based on standardised management and efficient corporate management, we strive to strike a balance between business interests and sustainable corporate development so as to enhance corporate reliability in terms of social responsibility.

We pay equal attention to both quality and innovation, maximising the value of our products and anchoring our social responsibility with the patient at the "centre". When the Company was first established in 2010, we have established a set of quality management system which has been certified by international authority to monitor the quality of our products. In 2020, we employed a R&D strategy that emphasizes internal as well as external qualities, synergizing our R&D centres in China and the US. By continuously enhancing our own innovation capabilities, complemented by the introduction of external quality resources, we have created a differentiated and diversified pipeline covering multiple new targets to truly meet the pressing clinical needs through accelerating differentiated innovation.

We work on the principle of win-win cooperation and are responsible for our suppliers and industry resources. We also maintain close communications with our suppliers and offer financial support to those who have reliable quality and stable cooperation, enabling the development of a healthy industry chain. Our global presence in mainstream and emerging markets is designed to bring affordable, high-quality products to more patients around the world. In addition, we strive to be an enabler of innovation, a trusted collaborator and a contributor to the global health industry through our participation in industry exchanges and technical collaborations.

We see the growth of people as the foundation of our business development. Therefore, we have established a fair and comprehensive recruitment and remuneration system. As we continue to enhance the professional competence of our staff and promote a culture of quality, we attract outstanding talent, especially innovative ones, to join our team. Through highly specific and practical training activities, we promote the development of talent, which in turn drives the development of the company, achieving a virtuous cycle of mutual growth and mutual benefit for both the company and the individual.

We are committed to practising green operations and reducing the environmental impact of our corporate activities. Under the premise of ensuring compliance with production and emissions regulations, Henlius has integrated its goal of resource conservation with initiatives to improve the efficiency of its operations. We are striving to build a green industry ecosystem by, among other methods, establishing a computerised quality management system to go paperless.

In 2020, we actively combatted the epidemic through drug development and technological research. Meanwhile, we also helped rural medical care and carried out charity and patient support activities. With the original aspiration of benefiting patients, the sincerity of giving back to society and the persistence of maintaining high quality of drugs, we are deeply committed to public welfare and effectively fulfilling the social responsibility of pharmaceutical enterprises.

In retrospect of the development of Henlius over the past decade, it has benefited from the support of the country, the high expectation from the society and the collaboration of all relevant parties in the industry. Looking forward to the future of Henlius in the next decade, we will uphold our original aspirations to bring health to patients with high-quality, affordable and innovative biologics. By sharing the fruits with society, we continue to promote human health development to achieve the core values of pharmaceutical enterprises, showcasing China's pharmaceutical innovation and development on the world stage.

## MAKING A CONCERTED EFFORT TO FIGHT THE COVID-19

The COVID-19 pandemic swept the world in 2020. Global pharmaceutical companies joined the fight against the coronavirus epidemic, kickstarting a battle against the pandemic. In view of the outbreak of the pandemic, Henlius took advantage of the pharmaceutical industry to pay close attention to the needs of the infected areas and organised material donations, fully demonstrating the social responsibility of the Company. Also, internal pandemic prevention measures were quickly deployed and all departments worked efficiently to ensure the health and safety of every employee.

### Dedicated to Fighting against the Pandemic and Achieving Breakthrough in Drug Research

The COVID-19 pandemic is a serious battle between human beings and a major infectious disease around the globe. A global innovative biopharmaceutical company, Henlius actively leverages its efficient in-house R&D capabilities and collaborates closely with its partners to contribute more technology to the global fight against the pandemic.

During the reporting period, Henlius actively invested in the research of COVID-19 prevention and treatment drugs. The company's HLX71 (ACE2-Fc fusion protein) for the treatment of SARS-CoV-2 and HLX70 (anti-S1 fully human monoclonal neutralizing antibody), developed in collaboration with its partners, received the project initiation and approval under COVID-19 Emergency Project in Key Projects from the *National Key R&D Programmes Public Security Risk Prevention and Control and Emergency Response Technology and Equipment*. As of December 2020, both products have received clinical trial approvals from the US FDA. The Company has then accelerated the preparation of the relevant clinical trials and the first healthy subject has been dosed in a Phase 1 clinical trial of HLX71 in the US.

#### Henlius ACE2-Fc Fusion Protein HLX71——a Possible Solution to Address the Unmet for Treatment of Patients with Moderate to Severe COVID-19



On 6 November 2020, HLX71, an ACE2-Fc fusion protein independently developed by Henlius for the treatment of COVID-19, was approved by the US FDA in clinical trials. On 14 April 2021, the dosing of HLX71 to the first healthy subject in a Phase 1 clinical trial was completed in the United States, promising not only to address the unmet needs for treatment in patients with moderate to severe COVID-19, but also to be applied to the prevention of COVID-19.

HLX71 is a recombinant hACE2 fusion protein with IgG1 Fc at the C-terminal, which is independently discovered and developed by Henlius. Binding of the RBD domain on the S1 subunit of the viral spike protein with hACE2 will lead to cell endocytosis of the virus, which is a critical step for viral entry. Because of its nature of an ACE2 fusion protein, HLX71 has dual mechanism of action in prevention and treatment of COVID-19. On one hand, the ACE2 part of HLX71 can act as a bait to bind with the viral RBD domain with a high affinity, preventing the binding of virus and host cell ACE2. Via this mechanism, the ACE2-Fc fusion protein can inhibit SARS-COV-2 virus infection and can be potentially used in the treatment of COVID-19. Besides, with ACE2 enzymatic activity, HLX71 can also inhibit inflammatory reaction by regulating the renin-angiotensin signal pathway thus enhancing its effect in treatment of COVID-19.



Non-clinical pharmacology, pharmacokinetics and toxicology studies were performed by Henlius to evaluate the efficacy and safety of HLX71 according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines. Results from these studies showed that HLX71 can significantly inhibit SARS-CoV-2 virus infection with a good safety profile via intravenous injection and was sensitive to neutralise all pseudovirus mutant SARS-CoV-2 strains which has been tested. It's worth noting that, HLX71 has demonstrated stronger neutralizing activity in the binding of some pseudovirus mutant SARS-CoV-2 virus.

#### Dedicated to Patients and Facilitating Treatment

During the COVID-19 pandemic, Henlius' trial programme in two hospitals in Wuhan was severely affected. As two subjects from each of the two hospitals were in the middle of the trial period, the four subjects were unable to return to the hospitals for trial-related treatment and investigations as planned due to the escalating infection control. After confirming the wishes to continue the dosing from the four subjects, the Company actively mobilised all parties to formulate detailed guidance documents and risk plans, taking into account the premise of complying with the quality management standard for drug clinical trials. Both above address integrated needs: protecting the benefits, safety and privacy of the subjects, standardising the trial operation and ensuring data integrity. The Company then coordinated with local cold chain transport company.

After the team's efficient and responsible work in securing the drug use, the four subjects were able to continue their drug use during the Wuhan epidemic closure. Hence, they expressed their deep gratitude to the investigators and the research team for putting the patients' interests first and overcoming many difficulties.



#### The Process of Securing Drug Use for Subjects in the Wuhan Clinical Programme During the Epidemic

#### 1. Full respect for the subject's wishes:

Inter-hospital treatment is carried out after confirmation of the subject's clear intention to administer the drug and confirmation with the local hospital that has the conditions to administer the process.

#### 2. Conducting benefit-risk evaluation for the subject:

The investigator was asked to assess the overall benefit of the subject's entry into the trial and to give a preliminary opinion on whether he/she agrees to the subject's continued use of the drug.

3. Compliance assurance :

Communicate with all parties, prepare appropriate risk plans and obtain agreement from the management body.

#### 4. Cryogenic transport and storage of drugs:

Contact pharmacies and test drug storage warehouses to provide drugs.

Contact cold chain transport companies that are qualified to deliver and ask the transport company and the recipient of the medicine to retain the delivery note and file it in the relevant folder as a project document. Once the medication is received by the recipient, it is stored in accordance with the storage conditions and the storage temperature is recorded.

#### 5. Dosing process management:

Qualification assessment and training of local investigators and dosing operators are completed prior to giving dosing to the subject.

The subject should go to the local hospital for relevant tests and inform the investigator of the relevant test results in good time before dosing and keep them in a safe place. The investigator will be asked to assess whether the subject is physically capable of administering the drug. If the conditions are met, proceed with the dose and undertake remote monitoring of the dosing process when conditions permit. If not met, discontinue the dose.

#### 6. Test data integrity assurance:

At the end of each dose, the subject keeps all examination and documentation required for the project and brings the information back to the study centre after the normal visit.

The investigator reviews and files the data to ensure the integrity of the data information throughout the test.

#### Dedicated to Society by Racing against the Clock to Offer Supplies to Assist the Infected Areas

During the pandemic, Henlius paid close attention to the needs of the infected areas and helped to win the battle of pandemic prevention and control through offering supplies and other means. During the reporting period, Henlius noticed that Wuhan, the center of the epidemic area, was under tremendous pressure to prevent the epidemic and needed urgent support for protective clothing, masks, medical equipment, first aid equipment and other epidemic prevention materials. Hence, the Company donated two batches of supplies in support of the fight against the pandemic (with a total value of RMB 1.18 million), including protective clothing, masks, portable ultrasound machines, infusion pumps, cardiac monitors and other equipment, in cooperation with Shanghai Fosun Foundation, to support the front medical team in Hubei to fight the pandemic together. At the beginning of 2021, a suspected case was found in the Xuhui Hospital of the Fudan University Shanghai Cancer Center and the hospital was closed in an emergency. Once again, Henlius joined Shanghai Fosun Foundation to donate RMB 400,000 to actively provide support and help. With the joint efforts of all parties in the society, the hospital strictly implemented the requirements of epidemic prevention and control and ensured that the overall operation was smooth and orderly. Thus, the epidemic was quickly controlled and daily medical services resumed.

#### Dedicated to Employees, Resuming Production and Work in an Orderly Manner

After the outbreak of the epidemic, Henlius set up a task force team and leading group for COVID-19 prevention and control. With the participation of the CEO's Office, Human Resources Department, Environment, Health and Safety Department, Administration Department and other departments, the Company coordinated management and resources from top to bottom to effectively protect the health and safety of employees.

In addition, Henlius timely issued various prevention and control statements such as Notice to All Employees on Response to COVID-19, Emergency Response Plan for COVID-19, Reference Manual for Prevention and Control of COVID-19 and Disinfection Guidance, as well as return to work policies such as Henlius' Return to Work Arrangement and Remote Working Guide and Supplementary Announcement on Travel Policy during the Prevention and Control of COVID-19 to resume work and production in an orderly manner while ensuring employees' health and safety.

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#### The Actions of Henlius for COVID-19 Prevention and Control

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Pre-holiday supplies and awareness-raising More than 1,000 masks and medicines were urgently purchased and distributed to employees to ensure their self-protection when they return home,thus abiding by WHO recommendations on preventive measures against the pandemic.	Communication channel establishment Established communication channels for epidemic situations and set up the "Henlius Health Daily Updates Group" to collect and track departmental health situations on a daily basis.	All staff notification/ disinfection campaign Established a statistical register of information for abnormal personnel; carried out daily disinfection of the Company area.
Frontline security Emergency provision of masks for Wuhan employees; strong support from labor unions to coordinate follow-up supplies for prevention and control.	Supplies coordination Material team kept communicating with various distributors to coordinate the epidemic prevention materials; weekly issuance of masks for employees returning to work.	Establishment of leading group for COVID-19 prevention The President took the lead in setting up a leading group for prevention and control and promulgate various guidelines for prevention and control and operations during the epidemic.
Health tracking after		

### Health tracking after resumption of work

Launched health reporting scheme upon returning to work; tracked daily health conditions; conducted daily disinfection of all office common areas.

#### Notice to All Employees on Response to COVID-19 was issued to all the staff in order to strengthen prevention and control for the epidemic

#### Communication team

Communication and tracking of health conditions, reporting of unusual situations, communication with the government, distribution of anti-pandemic updates, etc.

Henlius Task Force Team for COVID-19 Prevention and Control

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#### Human resource team

Tracking and investigation of staff activities, daily temperature screening, caring for staff in quarantine, patients and their family, staff education, flagging fake news, etc.



Preparation of anti-pandemic materials for sanitisation, protection, regular testing, etc.

#### Environmental control team

Sanitisation and ventilation management, monitoring of department sanitisation work, daily temperature screening, antipandemic training.



An electronic version of Reference Manual for Prevention of COVID-19 was distributed. Besides, training and guidance on epidemic prevention were conducted through the Company's internal platform, "Henlius University", to enhance employees' awareness of self-protection

# COMPANY OVERVIEW

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### **About Henlius**

Henlius (2696.HK) is a global biopharmaceutical company with the vision to offer highquality, affordable and innovative biologic medicines for patients worldwide with a focus on oncology, autoimmune diseases and ophthalmic diseases. Up to date, 3 products have been launched in China, 1 in the European Union (EU), the New Drug Applications (NDAs) of 3 products accepted for review in China. Since its inception in 2010, Henlius has built an integrated biopharmaceutical platform with core capabilities of high-efficiency and innovation embedded throughout the whole product life cycle including R&D, manufacturing and commercialisation. It has established global R&D centers and a Shanghai-based manufacturing facility certificated by China and the EU Good Manufacturing Practice (GMP).

Henlius has pro-actively built a diversified and high-quality product pipeline covering over 20 innovative monoclonal antibodies (mAbs) and has continued to explore immuno-oncology combination therapies with proprietary serplulimab (anti-PD-1 mAb) as backbone. Apart from the launched products 汉利康<sup>®</sup> (rituximab), the first China-developed biosimilar, 汉曲优<sup>®</sup> (trastuzumab, Zercepac<sup>®</sup> in the EU), the first China-developed mAb biosimilar approved both in China and in the EU and 汉达远<sup>®</sup> (adalimumab), the Company's first product indicated for autoimmune diseases, the NDA of innovative product serplulimab indicated for MSI-H solid tumors has been granted priority review, and the NDAs of HLX04 (bevacizumab) and HLX01 (rituximab) for the treatment of rheumatoid arthritis are also under review. What's more, Henlius has conducted over 20 clinical studies for 10 products and 8 combination therapies worldwide, expanding its presence in major market as well as emerging market.

#### Henlius in 2020



#### Governance

An ESG Committee was established under the Board of Directors to oversee the ESG work of the Company

#### **Compliance Operation**

1 anti-corruption compliance training session for executives

9 anti-corruption compliance training sessions for employees

Reached more than 1,200 employees

**O** lawsuits and cases involving corruption or unfair competition

#### **Intellectual Property**

Applied for 21 invention patents

Obtained 12 invention patent authorizations

Obtained the *Enterprise Intellectual Property Management* (GB/T29490-2013) certification

#### **Enabling Innovative R&D**

3 products launched in China

1 product launched in the EU

3 products under NDA review in China

20+ clinical trials

As of April 2021

:12

### Benchmarking with International Quality

Certificated by International Authorities

Xuhui Facility with its supporting quality management system received the GMP certification in both China and EU

#### **Building Quality-oriented Culture**

Quality training hours 82,945 hours

Reached 733 employees Average training hours per capita 113.16 hours

#### **Ensuring the Safety of Drug Use**

The only pharmaceutical company in Shanghai region to receive the award "Outstanding enterprises for the evaluation of ADR Monitoring in 2020"



#### **Forging Responsible Supply Chains**

Improved business continuity while reducing costs and increasing efficiency through localization or increasing supply channels

#### **Carrying out Technical Cooperation**

Collaborated with companies such as Cytiva and Fosun Kite to work on technology upgrade and empower industry innovation

#### **Expanding Business Topology**

Signed commercial cooperation agreements with oversea partners such as Accord, Essex, Mabxience

External licensing of products covered the mainstream market in Europe and the United States and many emerging countries

#### **Promoting Industry Development**

Promoted the development of biopharmaceutical industry in China, in concreted cooperation with industry partners, by conducting research training, school-enterprise cooperation, leading projects such as the compiling of biosimilar science book



#### Employment

#### Steep Increase

A total of 1,873 employees, seeing an increase of 59.81% over 2019

#### High-caliber Talent

Bachelor's degree and above weigh 84%

Master's degree weigh 29%

Doctoral degree weigh 5%

#### **Employee Development**

#### **Employee Training**

Employee training hours per capita reached 17.61 hours, seeing an increase of 35.57% over 2019

#### On E-Learning platform

Completed 172 internal learning sessions

Completed 169 external learning sessions

Totalled 5,056 person-times

#### **Employee Caring**

Communications

Employee Engagement scored at 84

Organisational Support scored at 83

#### Safety

Provided a total of 43,507 hours of EHS training with 8,717 person-times

Safety drills reached 1,835 persontimes

O major safety accidents for employees



#### **Green Productions**

 $\begin{array}{l} \mbox{Comprehensive energy consumption} \\ \mbox{intensity was $2.89$ GJ/ RMB 10,000 of} \\ \mbox{revenue, $66.44\%$ lower than that of} \\ \mbox{2019} \end{array}$ 

Water consumption intensity was 3.98 cubic metres / RMB 10,000 of revenue, 66.53% lower than that of 2019

Solid waste emission intensity was 10.18 KG/RMB 10,000 of revenue, 68.64% lower than that of 2019

Packaging material consumption intensity was 0.73 KG / RMB 10,000 of revenue, 14.54% lower than that of 2019

#### **Green Operations**

Paperless office saves paper usage of 451,889 sheets



Donated to charity organisations RMB **7.6** million

Received 6 charity awards

Creating a Diversified Ecosystem of Diagnosis and Treatment

Officially launched "Leaving No HER2 Positive Patient Behind" diagnosis and treatment ecosystem

#### **Supporting Rural Primary Care**

Officially launched "汉曲优 Rural Medical Service – Public Welfare Activity" with over 10 experts participating and 2 counties covered

#### **Honour and Recognition**

#### Awards

The 4th "Golden Hong Kong Stocks" Most Valuable Pharmaceutical and Medical Stock Companies

China Pharmaceutical Brand with Greatest Growth Potential (汉利康®)

Changchun Award "2020 Innovative Pharmaceutical Enterprise"

China Innovation New Power in Pharmaceutical Industry

Jinzhi Award "The Most Valued Top 10 in Biopharmaceutical Industry"

PharmaBIGStar "2020 China's Top 50 Most Innovative Companies in Biomedicine"

2020 The Best Listing Company Best Information Disclosure Award

The 16th China Global Awards for Excellence in Public Relations Social Responsibility Bronze Award

The 5th "Social Value Co-creation" Excellence Award

Shanghai Model Group (Henlius HLX-01 Project Core Team)

Eight Charity Projects of ONE FOSUN Charity Week

The 13th China Health Annual Forum · Top Ten New Medicine (汉曲优 ®)

Most Innovative Global Biopharmaceutical Company 2021

National Worker Pioneer (Henlius HLX-01 Project Core Team)

#### **Awarding Institutions**

Zhitongcaijing.com

Pharmaceutical Economics Newspaper

Jiemian.com

China National Pharmaceutical Industry Information Center

JRJ.COM

Emedclub.com

Gelonghui

China Public Relations Association

CCM CSR Promotion Center

Shangh<mark>ai Mun</mark>icipal Party Committee, Shangha<mark>i Munici</mark>pal Government

Shanghai Fosun Foundation

People's Daily Health app, health.people.com

Global Health & Pharma

All-China Federation of Trade Unions

#### **Government Support**

National Key R&D Program "Public Security Risk Prevention and Control and Emergency Response Technology and Equipment" Key Special Project- COVID-19 emergency project

National Technological Transformation Project (Songjiang Facility)

Shanghai Major Construction Projects, Shanghai Strategic Emerging Industry Projects (Songjiang Facility)

Xuhui Enterprise Technology Research Centre

Postdoctoral Program in Pudong New Area

Shanghai Anti-tumor Biologic Medicine Engineering and Technology Research Centre

#### **Company Strategy**

The overall strategy of Henlius is to "maximise biosimilar commercial value, while relying on self-innovative R&D capability complemented with external collaboration and license-in, as well as accelerate innovation with full speed". In terms of R&D, Henlius strives to synergise China and US R&D centers and to strengthen translational medicine capability, advancing differentiated innovation. In terms of production, under the premise of guaranteeing "Henlius Quality", Henlius further improves manufacturing capacity and optimises production technology to create competitive economies of scale. In terms of commercialisation, through innovative marketing, access and commercialisation strategies and efficient sales execution capability, Henlius builds the industry's top commercial team.



- Covering both mature and emerging markets
- Proactively steering forward the internationalisation of selected early-stage innovative products

#### **Product Pipeline**

Product (Reference Drug)		Target	Indication	Pre-clinical IND	Phase 1 Phase	_	NDA	Launched	Parti	-	
Marketed products	<sup>3</sup> 汉利康 <sup>®</sup> (rituximab) <sup>①</sup>		CD20	Non-Hodgkin lymphoma and chronic lymphocytic leukemia						FOSUN PHARMA 期星医的	(CÁBMA)
eted pr	汉曲优 <sup>®</sup> (tr	曲优 <sup>®</sup> (trastuzumab) <sup>②</sup> HER2		Breast cancer and metastatic gastric cancer	The first Chinese mAl	biosimilar launch	ed in both Chin	a and the E	U	accord Jacobson Jacobson	mAbxience
Mark	<sup>業</sup> 汉达远 <sup>®</sup> (adalimumab) <sup>(3)</sup>		TNF-α	Rheumatoid arthritis,ankylosing spondylitis, psopiasis and uveitis						25 万邦医药	FOSUNPHARMA R R & R R R R R R R R R
n Alfry	HLX01 (rituximab) HLX04 (bevacizumab)		CD20	Rheumatoid arthritis <sup>(4)</sup>						FOSUN	PHARMA IEE PA
n near-terr ercial visit			VEGF	Metastatic colorectal cancer and non-squamous non-small cell lung cancer							
Comme	HLX10 (se	rplulimab) <sup>(5)</sup>	PD-1	MSI-H solid tumours 2L+					Under NDA priority review	Хка	bio
		Monotherapy	PD-1	Chronic hepatitis B							
				Metastatic esophageal squamous-cell carcinoma 1L							
		+Chomo	PD-1	Squamous non-small cell lung cancer 1L	Global multi-centre cli	nical trial					
		+Chemo	PD-1	Extensive-stage small cell lung cancer 1L	Global multi-centre cli	nical trial					
	HLX10 (serplulimab)	)		Neo-/adjuvant treatment of gastric cancer	Global multi-centre cli	nical trial					
		+HLX04	PD-1+VEGF	Non-squamous non-small cell lung cancer 1L							
				Hepatocellular carcinoma 1L							
				Metastatic colorectal cancer 1L							
		+HLX07	PD-1+EGFR	Squamous-cell carcinoma of the head and neck 2L							
arch	HLX07 <sup>(6)</sup> EGFR		EGFR	Solid tumours							
resea	HLX05 (cetuximab) (7)		EGFR	Metastatic colorectal cancer and squamous-cell carcinoma of the head and neck						<u> Sin</u>	gze
Under clinical research	HLX12(ra	mucirumab)	VEGFR2	Gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer							
er cl	HLX20 <sup>(8)</sup>		PD-L1	Solid tumours							
Dnd	HLX22		HER2	Breast cancer and gastric cancer							
	HLX55 <sup>(9)</sup>		c-MET	Solid tumours							
	HLX11 (pe	ertuzumab)	HER2	Breast cancer							
	HLX14 (denosumab) HLX71 <sup>(10)</sup>		RANKL	Osteoporosis							
			S1 Protein of SARS-CoV-2	COVID-19							
	HLX04-O	11)	VEGF	Wet age-related macular degeneration	Global multi-centre cl	inical trial				ESSE	() IZ IE
	HLX26 HLX13 (ipilimumab)		LAG-3	Solid tumors and lymphomas							
			CTLA-4	Melanoma, renal cell carcinoma and metastatic colorectal cancer							
	HLX56 <sup>(12)</sup>		DR4	Solid tumours							
	HLX70 <sup>(10)</sup>		S1 Protein of SARS-CoV-2	COVID-19							
	HLX15 (daratumumab)		CD38	Multiple myeloma							

(1) Approved by the NMPA in February 2019, being the first domestic biosimilar.
(2) Approved in the EU In July 2020 (EU brand name: Zeropar, \*); 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) ND approved in China, the United States,
(7) Commercialisation rights in China and terbuine contraines in Southeast, Central and South Asia were obtained
(10) ND approved in the United States, and certain countries in Southeast, Central and South Asia were obtained
(11) ND approved in Australia.
(2) Commercialisation rights in China were obtained.
(2) Commercialisation rights in China were obtained.
(3) IND approved in Australia, the United States, and the EU.
(3) Commercialisation rights in China were obtained.
(4) Commercialisation rights in China were obtained.
(5) Commercialisation rights in China were obtained.
(6) IND approved in Australia.
(7) Commercialisation rights in China were obtained.
(7) Commercialisation rights in China were obtained.
(8) ND approved in Australia.
(9) Commercialisation rights in China were obtained.
(10) ND approved in Australia.
(11) ND approved in Australia.
(12) Commercialisation rights in China were obtained.
(12) Commercialisation rights in China were obtained.
(13) ND approved in Australia.
(14) ND approved in Australia.
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(17) ND approved in Australia.
(18) ND approved in Australia.
(19) ND approved in Australia.
(19) ND approved in Australia.
(10) ND approved in Australia.
(11) ND approved in Australia.
(12) Commercialisatin the Unite

**Company Footprint** 



## **Sustainable Development Management**

Our CSR vision has its root in our corporate culture. The mission of "improving patients' lives by timely providing them with quality and affordable protein therapeutics through technical innovation and operational excellence" and the vision of "being the most trusted biotech company providing innovative and affordable medicines for all patients" give strong support to Henlius when it comes to fulfilling its promises for stakeholders. The Company has also been upholding the unity of corporate economic responsibilities and social responsibilities.

#### **CSR Vision**

The CSR model of Henlius is based on responsible business operation. It combines responsibilities for employees, society and partners in pursuing the CSR goal of improving patients' lives by timely providing them with quality and affordable protein therapeutics through technical innovation and operational excellence.

In order to better implement the work



#### Henlius CSR Model

vision of sustainable development at the Company's strategic level, continuously improve the Company's ESG work system and ensure that the Company makes decisions on various ESG matters in a scientific and efficient manner, Henlius established the Environment, Social and Governance Committee (the "ESG Committee") under the Board of Directors during the reporting period and set up an ESG task force group to coordinate the Company's ESG work. It is therefore hoped to achieve sustainable corporate development through management with clear division of authority and responsibility.



#### **Communications with Stakeholders**

The sustainable development of Henlius cannot be achieved without the win-win cooperation with various stakeholders. In order to comprehensively understand the needs of stakeholders and widely listen to the expectations of the community for the Company, the Company identifies stakeholders closely linked to the development of the Company based on its business scope and operating nature, creates diversified communication channels, and establishes a real-time, effective and long-term communication mechanism. In addition, the Company responds to stakeholders with specific responses. During the reporting period, Henlius involved stakeholders in major decisions and strategic adjustments of the Company through various forms (formal or informal, online and offline) to understand stakeholder demands and expectations.

Stakeholders	Concerns	Communication channels	Frequency/ Number of times
Shareholders and investors	Economic performance Business compliance Risk management Product innovation and R&D Product safety and quality Business ethics	- Stock holder meeting - Earnings conferences - Results announcement - Announcements - On-site visits	- 7 shareholder meetings - 46 investor conferences - 2 earnings conferences - 123 announcements - Occasional on-site research
Government and regulators	Business compliance Industrial cooperation and development Product safety and quality Business ethics Product innovation and R&D Emission management Energy use	- Participating in industry standards formulation - Participating in policy formulation - Providing suggestion - Participating in government projects	- No less than 5 times
Partners	Industrial cooperation and development Commercial cooperation	- Industry exchanges - Exploring global cooperation - Meetings	- No less than 30 times for industry exchanges - Global cooperation and meetings are held occasionally
Clients	Drug availability Responsible marketing Business ethics Client information and privacy protection Client satisfaction and communication	<ul> <li>Establishing customer service process and customer compliant handling process</li> <li>Conducting customer satisfaction survey</li> <li>Meetings</li> </ul>	- 24/7 Product hotline
Employees	Employee communication and benefits Employee rights protection Employee health and safety Employee retention and development Employee satisfaction	<ul> <li>Performance review meetings         <ul> <li>Internal email</li> <li>Trade union and congress of employees</li> <li>Employee caring activities</li> <li>Employee training, performance management and promotion</li> <li>Employee satisfaction survey</li> </ul> </li> </ul>	<ul> <li>No less than twice for performance review meetings</li> <li>No less than 5 times per month for internal email</li> <li>No less than 4 times for quarterly staff meetings, trade unions and congress of employees</li> <li>No less than 12 times for employee caring activities</li> <li>No less than once for promotion</li> <li>No less than once for employee satisfaction survey</li> </ul>
Suppliers	Sustainable supply chain management Business compliance Business ethics	- Supplier audit and communications - Green supply chain management	- No less than once a year
Media and the public	Industrial cooperation and development Business Ethics Product safety and quality Product innovation and R&D Public welfare	-Information disclosure -Official website -Press release -Press conferences/media briefings	- Real time information disclosure - Real time update of official website - 268 press releases - Press conferences / media briefings 3 times
Communities	Emission management Energy use Community and public welfare	- On-site survey - Charity projects - Analysis of environmental impact and management	- No less than once a year

#### Materiality Issue Analysis Process



#### **Analysis of Materiality Issues**

Identifying and analyzing materiality issues is the foundation of good corporate sustainability management. During the reporting period, Henlius benchmarked itself against leading domestic and international peers and conducted more than ten in-depth on-site interviews with internal stakeholders, and collected stakeholders' views on the Company's CSR and sustainability management and disclosure at a number of large-scale events held in China. Based on the feedback from stakeholders, Henlius sorted out in detail the ESG issues that are more consistent with the Company's development strategy. Combining the evaluation results with the stakeholder feedback results, the Company considered the issues that are of greater concern to stakeholders and are consistent with strategic development direction as highly significant and materiality issues.

The results of the materiality issue analysis are presented in the form of a materiality issue matrix. Materiality issues that are in line with the Company's direction and of high materiality to stakeholders are located in the upper right-hand corner of the matrix and are particularly important to the creation and maintenance of value for the Company. They are described in detail in this report.

In the end, the Company summarised 21 issues, nine of which were identified as highly important, namely industrial cooperation and development, employee communication and benefits, product innovation and development, employee training and promotion, corporate governance, anti-corruption and business ethics, inclusive healthcare, product quality and compliance. The relevant information is presented in detail in this report.



#### Henlius Materiality Issues Matrix

# FOUNDATION OF RESPONSIBILITIES FULFILMENT: EXCELLENCE IN DEVELOPMENT

Through a sound corporate management mechanism, Henlius protects the rights and interests of shareholders, enhances corporate value, and ensures sound business development, thereby enhancing its ability to assume social responsibility. The Company strictly complies with the requirements of the *Company Law of the People's Republic of China, the Securities Law of the People's Republic of China, the Securities Law of the People's Republic of China, the Code of Corporate Governance for Listed Companies, the Corporate Governance Code in Appendix 14 of the Listing Rules of the Hong Kong Stock Exchange,* and other laws, regulations and regulatory documents. The Company will continue to improve its corporate governance structure, with the General Meeting of Shareholders, the Board of Directors and the Supervisory Committee overseeing the strategic decisions and management of the Company to enhance the effectiveness of governance and protect the legitimate rights and interests of shareholders.



## Corporate Governance

The Company is steered by an efficient Board of Directors, which monitors the Company 's business, strategic decisions and performance, and makes objective decisions in the best interests of the Company. The Board has established a total of five committees, namely, Audit Committee, Compensation Committee, Nominating Committee, Strategy Committee and ESG Committee, for overseeing particular aspects of the Company's affairs. The Company has also in place a corporate governance framework and has established a set of policies and procedures based on the Code of Corporate Governance. Such policies and procedures provide the infrastructure for enhancing the Board's ability to implement governance and exercise proper oversight on business conduct and affairs of the Company. The Board believes that high corporate governance standards are essential for the Company to safeguard the interests of Shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability.

As of the end of the reporting period, the Company's Board of Directors consists of 10 directors, including one executive director, four independent non-executive directors and five non-executive directors: with one being a female director. All of the current directors of the Company have rich industry experience and good educational background, and 40% of the directors have obtained a doctoral degree.

# **Compliance Operations and Optimised Management**

#### Compliance Culture and Business Ethics

The Company regards compliance culture and high standards of business ethics as the foundation of its responsible operations. The Company strictly complies with laws and regulations and compliance standards of regulatory bodies, including the Pharmaceutical Administration Law of the People's Republic of China, the Reaulations for the Implementation of the Drug Administration Law of the People's Republic of China, the Advertising Law of the People's Republic of China, the Anti-Unfair Competition Law of the People's Republic of China, the Anti-Monopoly Law of the People's Republic of China, the Interim Provisions on the Prohibition of Commercial Bribery in Pursuing Business Goals, Foreign Corrupt Practice Act etc., and formulates and issues the Anti-Corruption Regulations, Regulations on the Management of Employees' Integrity in Practice and Measures on the Management of Acceptance of Gifts in Official Activities, etc. to strengthen internal governance and control, guide employees to perform their duties with integrity and trustworthiness, and create and maintain a clean cultural environment for the Company. The above promote the Company's compliance construction, prevent the occurrence of acts that harm the interests of the Company and shareholders, and ensure the healthy, stable and sustainable development of the Company.

In addition, Henlius has established the Codes

of Conduct and Supporting Policies to effectively promote employee compliance in conducting business with healthcare professionals (HCPs), government officials, and third-party business partners, thus ensuring that the Company operates in compliance.

The Company also built a Compliance Commission to ensure compliance rules and commercial ethics are well honored in every link of the business operation and prevent bribery, blackmailing, fraud and money laundry from happening.

At the implementation level, the Legal and Compliance Department, Audit Department, Finance Department, Human Resources Department and other relevant departments work together to adhere to the prevention-oriented, punishment and prevention at the same time policy. By jointly establishing and continuously improving internal supervision and reporting channels and processing procedures, it is hoped to promote the Company's integrity and compliance construction.

In addition, for third-party partners, the Company requires them to honor business ethics and sign a letter on *Anti-Commercial-Bribery* as a way to regulate their acts. In accordance with the *Codes of Conduct and Supporting Policies*, through the third-party platform, the Company conducts on-line due diligence investigations on its third-party partners to identify risks in compliance.



#### Procedure to Report Wrongdoings Regarding to Business Compliance in Henlius



Human Resources Department and related business department will get involved to verify evidence if an official investigation is initiated

#### **Reporting and Handling**

In order to ensure that violations are handled through standardised and effective feedback channels, Henlius has developed and strictly implemented Regulations on Reporting and Dealing with Wrongdoings Relating to Business Compliance and Integrity and established open channels such as integrity reporting email channel, integrity reporting phone number and integrity letter addresses to receive relevant complaints. In the process of dealing with all violations, the Company follows the five principles of "encouraging reporting principle, truthful compliance principle, anti-retaliation principle, confidentiality principle, and avoidance principle".

After receiving the reported clues, the Legal and Compliance Department of the Company will evaluate the reported clues and, for clues that meet the conditions for filing a case. apply for investigation authorization and conduct a case investigation in accordance with relevant regulations. All violations that have been fed back through legal and compliant channels will be reported back to the whistle-blower within one month from the date of acceptance by the Company. The resolution of the whistle-blower on the reported incident will be returned to the whistle-blower within one month from the date of the resolution of the Compliance Commission on the reported incident for the violation whose investigation is completed.

Henlius takes the protection of the personal safety of whistle-blowers and witnesses as its responsibility and holds a zero-tolerance attitude toward retaliation. In accordance with the "confidentiality principle", the Legal and Compliance Department of the Company will keep the information of whistle-blowers



Five Handling Principles

and reporters strictly confidential. For those who violate the confidentiality of reporting, leading to leakage of reporting information; or for those who violate work discipline, leading to leakage the personal information of witnesses and retaliation or other serious consequences against the whistle-blower or witness and his relatives, the Company will, depending on the severity of the circumstances and the relevant provisions of the Company, pursue the person and other responsibilities. Those suspected of constituting a crime will be transferred by the Company to the judicial organs to pursue criminal responsibility according to law. During the reporting period, there were no lawsuits or cases involving corruption or unfair competition against Henlius.



During the activity, the Company fully mobilised the enthusiasm of colleagues on site through vivid and interesting compliance knowledge quiz. The crisis case sharing, and emergency drill effectively strengthened colleagues' understanding and helped them learn by heart the compliance knowledge. In addition, in order to keep up with the latest development of compliance management, a third-party law firm was invited to bring a compliance training on the theme of "Legal **Risk Prevention in Pharmaceutical** Marketing and Promotion".



#### **Integrity and Compliance Training**

In order to consolidate the compliance awareness of all employees, strengthen the concept of compliance operation, and form an effective compliance control operation mechanism in various businesses, Henlius has conducted various forms of compliance training for employees of different departments and roles.

During the reporting period, Henlius conducted one anti-corruption compliance training for senior management and nine anti-corruption compliance trainings for employees, covering more than 1,200 employees. Internal staff integrity training Henlius conducts regular compliance training for new recruits and employees in key positions at the beginning
of their employment so that the compliance culture holds appeal among employees on a daily basis. At the time,
the Company requires that all employees sign a letter of commitment to clean business with a view to strictly
guaranting process compliance and internal compliance management;

- During the reporting period, Henlius arranged centralised training (online or offline) for new employees on a quarterly basis, focusing on anti-corruption and compliance-related content, in order to convey the Company's compliance management environment and anti-corruption and anti-bribery concepts to new employees.
- With the launch of the products, Henlius will further strengthen the compliance promotion of the product comprehensively, adhere to the real and scientific way of marketing, and provide objective and reliable product information for patients and hospitals;
- Internal and external compliance training
- In December 2020, Henlius added an anti-corruption compliance training session to the distributor meeting to convey the Company's anti-corruption philosophy. Meanwhile, Henlius emphasised compliance requirements in the partnership process;
- Intensive explanations and training on anti-corruption and compliance-related policies were held 3 times at internal regional meetings for colleagues (cumulative coverage of about 400 people);
- In December 2020, Henlius invited representatives from 14 meeting suppliers to conduct an online training related to anti-corruption compliance, conveying the Company's anti-corruption philosophy. At the same time, compliance requirements were emphasised at meetings/events.

#### **Information Security**

Since its incorporation, Henlius has placed a high priority on data security and business information protection, and has implemented strict management processes within the Company, which has always maintained a good track record.

Henlius formulates and implements an information security management system with the Information Security Management Manual as the general framework, supplemented by the Information Security Management System for Personnel, Network Security Management System, Information System Operation Procedures and other systems, thus implementing the information security management system standards. The Company also aims to improve information security management, maintain the security and stability of the Company's information system, and achieve the security protection level of business information and system services.

At present, the Company has established a comprehensive information security management group and clarified the responsibilities of each member of the group. Henlius adheres to the information

security policy of "full participation, clear responsibility, prevention-oriented, rapid response, risk control, and continuous improvement" and promotes the active defense concept of prevention-oriented information security, as well as rapid and orderly response to information security incidents. The Company also implements the concept of risk management by regularly conducting risk assessment and control of "mail system", thus managing the information security risk to an acceptable level. In accordance with the PDCA(Plan, Do,Check and Action) principle, Henlius continuously improves the Company's information security work to ensure that the information systems are secure and controllable, as well as the development and maintenance of information systems security and stability.

In addition, Henlius continuously improves the information security awareness and capability of all employees through regular information security promotion, education and training. For employees in the Information Technology Department and non-IT employees, the Company conducts targeted training for them in a differentiated manner to strengthen their information security awareness.

#### **Responsible Publicity**

All publicity activities carried out by Henlius strictly comply with the requirements of applicable laws and regulations and industry guidelines in the place of operation. Among them, information that may have a significant impact on the brand image and operation of the Company is managed by the Company's Public Relations Department, which covers, but not limited to, establishing a press release team to release corporate press releases, receiving visits from external media, organising and planning press conferences, and aligning the Company's external information disclosure.

The press release working group communicates with external media on behalf of the Company and completes press releases, etc. By introducing the Company's development and informing major milestones, Henlius maintains smooth and efficient communication between the Company and the public. Without authorization, all staff members of the Company are not allowed to release company information to the public in their personal or company name.

## **Intellectual Property Right Protection**

Intellectual property(IP) is part of the core competitiveness for enterprises, especially for technology-based ones. Henlius adheres to the IP management policy of *Encouraging Invention and Creation to Improve Market Competitiveness*, and continues to improve the IP management system and the infringement accountability system. During the reporting period, the Company has obtained the certification of *Enterprise Intellectual Property Management (GB/T* 29490-2013).

In accordance with the Trademark Law of the People's Republic of China, the Patent Law of the People's Republic of China, the Copyright Law of the People's Republic of China and the Law of the People's Republic of China Against Unfair Competition, Henlius has built an intellectual property right (IPR) management system based on the Enterprise Intellectual Property Management (GB/T29490-2013). As of the end of the reporting period, with the Intellectual Property Manual as the overarching guiding document, the Company has secondary and procedure documents including the regulations for IP management, confidentiality management, and incentives and punishment for intellectual properties. These documents explain how to maintain information confidentiality, control IPrelated risks and provide dispute response mechanisms, and strictly investigate and control IP risks. The Company's R&D center in California has adapted the above system and documents to the local laws and regulations to form the IPR management system and control plan for itself. As a result, a unified IP management system is formed in both locations, while taking into account the independence of regulatory differences.

During the reporting period, Henlius applied for a total of 21 invention patents and received 12 invention patent authorizations. The patent applications and acquisitions of Henlius from 2019 to 2020 are as follows.



#### Patent Applications and Acquisitions by Henlius from 2019 to 2020



#### **Intellectual Property Protection Initiatives**

Henlius combines the construction of IP culture with the development of the Company and promotion of IP culture throughout the Company. Through daily work communication as well as in-depth publicity and training at all levels, the IP awareness of all employees in the Company has been improved.



Multi-channel promotion

Fully utilising the corporate website, WeChat channel, internal meetings, daily work collaboration and other methods to showcase the achievements of Henlius and promote the work of IP, training staff about IP.



Annual training plans to educate different levels of staff about IP internally as well as through the support of external experts and external exchange, in order to enhance the overall IP knowledge of the Company.



All-round enhancement

Deploying staff to participate in national, municipal and regional IP seminars and meetings to actively influence society. At the fifth China Pharma Intellectual Property Summit and meetings organised by PhIRDA and the National Medical Products Administration, IP representatives of the Company gave a number of informative presentations regarding biomedicine IP.



#### **Multi-Level Training System**

During the reporting period, Henlius organised two R&D-type IPR trainings within the Company, dispatched corporate executives to attend one IPR professional training abroad. IPR professionals were also dispatched to attend more than 10 external IPR professional trainings and conferences. In addition, the Company trained one professional who was qualified as a patent worker in Shanghai. During the reporting period, there was no litigation case related to IP rights of Henlius.

#### Intellectual Property Awareness Promotion Channel



## INNOVATING WHILE MAINTAINING QUALITY

As a global innovative biopharmaceutical company, Henlius is dedicated to offering highquality, affordable and innovative biologic medicines for patients. Since its establishment in 2010, Henlius has built an integrated biopharmaceutical platform with highly efficient and innovative core capabilities embedded throughout the whole product life cycle including R&D, manufacturing and commercialisation. The Company actively pursues science- and technologydriven research and development activities while ensuring the quality throughout the whole product lifecycle. Through continuous improvement of the quality management system, Henlius ensures that the products meets international quality standards and regulatory requirements, and that the product quality can be trusted for the benefits of patients worldwide.





## **Enabling Innovative R&D**

In 2020, Henlius continues its momentum for a diversified innovation by enhancing internal innovation capacities and reaching out to more strategic partners. For internal innovation capacities, the Company synergizes R&D centres in China and the US, advances its translational medicine capabilities and builds an efficient innovation organisation. Meanwhile, products with great potential are licensed in for increased R&D efficiency and diversified innovation. Building upon the accumulated resources and technologies in the field of biologic medicines, Henlius has been establishing a forward-looking presence in innovative targets, bispecific antibodies as well as the antibody-drug conjugates (ADC). With its anti-PD-1 product as core, Henlius has replenished a diversified and differentiated innovation pipeline covering the candidate targets with the aim of addressing some of the most significant unmet needs and gathering pace in commercialisation with full speed.

As of April 2021, Henlius has successfully marketed three products in China and one product in the EU. Three products have been accepted for NDA review in China. In 2020, the Company successfully marketed two products. Among them, 汉 曲优<sup>®</sup> (trastuzumab, Zercepac<sup>®</sup> in the EU), as the first Chinese monoclonal antibody biosimilar approved in both the EU and China, pioneered the participation of Chinese pharmaceutical companies in the world competition of monoclonal antibody biosimilars and further opened the way for the internationalization of domestic monoclonal antibody drugs, which is expected to bring high-quality and affordable treatment options to more patients worldwide.



As of April 2021

#### Three Products Successfully Launched

#### 汉利康。

In February 2019, 汉利康® (rituximab), the first product independently developed by Henlius, was approved by the National Medical Products Administration (NMPA). It became the first biosimilar drug developed and approved in China in accordance with the Technical Guidelines for the Development and Evaluation of Biosimilars (Tentative) released in 2015. In 2020, the shipment volume of 汉利康 ® amounted to approximately 720,000, among which, the shipment volume in the second half of the year amounted to approximately 520,000. As of the end of the reporting period, provincial medical insurance access work has been finished in 30 provinces and municipalities. Tendering process has been completed in 28 provinces and municipalities. Nearly 70% of the core hospitals have admitted it. Since its launch two years ago, 汉利康<sup>®</sup> has benefited more than 50,000 Chinese patients and has been well recognised by doctors, patients and the industry for its excellent product quality and effective clinical performance.



The first Chinese biosimilar The domestic commercial sales handled by The First Jiangsu Fosun, a subsidiary of Fosun Pharma, Accelerated The first Chinese rituximab with a professional sales team of nearly 400 people Approved for two new indications and new dosage form of 500mg/50ml/vial, as well as the addition of 2,000L production scale in 2020 • Following the four development guidelines for All-around National Science and Technology Major Project High in the 12/13th Five-year Plan of China —— Major biosimilar with head-to-head comparison with Quality Benefits originator New Drug Research & Development Project • Having benefited over 50,000 chinese patients in • Single use bioreactor technologies (2000L) adopted the past two years ever since its launch Awarded "Biosimilar Initiative of the Year" at Global Included in China's National Reimbursement Generics & Biosimilars Awards 2019 Drug List (NRDL) to lighten financial burden on patients and reduce public healthcare costs Phase 3 clinical study results published on JHO; Similarity studies of Pharmacology published on The first & the only rituximab that filed NDA for mAbs new indication of rheumatoid arthritis in China to benefit a wider patient population

#### 汉曲优<sup>®</sup>

汉曲优 ® (trastuzumab, Zercepac® in the EU) was successively approved by the European Commission (EC) and the NMPA in July and August 2020, being the first domestic monoclonal antibodies biosimilar approved in both China and the EU. It therefore pioneered the participation of Chinese pharmaceutical companies in the world competition of monoclonal antibodies biosimilars. With GMP certification in China and the EU, 汉曲优 ° corresponds to all the approved indications of the trastuzumab originator, and is expected to bring more treatment options to HER2-positive breast and gastric cancer patients worldwide with international quality. As of April 2021, Henlius has completed all the provincial medical insurance access work and tendering process in 30 provinces and municipalities, laying a strong foundation for benefiting more patients. As of the end of the reporting period, 汉曲优 <sup>®</sup> had successfully entered the National Health Service and a number of top hospitals in the United Kingdom as well as nearly 20 EU countries and regions including Germany, Spain, France, Ireland, Italy, Hungary, etc.



Approved in China and the EU	<ul> <li>The first approved Chinese trastuzumab biosimilar</li> <li>The first Chinese monoclonal antibody biosimilar approved in the EU</li> </ul>	Global Footprint	<ul> <li>Domestic market</li> <li>Consolidating the construction of the HER2-positive patient diagnosis and treatment ecosystem, including cooperation on healthcare professionals education, drug access, testing and diagnosis, big data, patient payment and patient education, with</li> </ul>
International Quality	<ul> <li>Following China and the EU biosimilar guidelines</li> <li>Manufacturing site and quality management system certificated by China and the EU GMP</li> <li>Evaluated in a multi-centre Phase 3 clinical study with a total of 649 patients enrolled and 89 clinical sites established across China, the Philippines, Poland and Ukraine</li> <li>Similarity studies of Pharmacology and Phase 3 clinical results published on <i>BioDrugs</i>;Phase 1 clinical results published on <i>Cancer Chemotherapy and Pharmacology</i></li> </ul>		<ul> <li>the aim of leaving no HER2-positive patient behind</li> <li>A supplemental new drug application (sNDA) for an additional 60 mg/vial has been accepted by the NMPA, benefitting more patients with more dosage form options and combination dosing regimens</li> <li>Biosimilar added in 2021 <i>Guidelines of Chinese</i> <i>Society of Clinical Oncology (CSCO) - Breast Cancer</i></li> <li>International market</li> <li>Product licenses reaching over 80 countries and</li> </ul>
Awards & Recognitions	<ul> <li>National Science and Technology Major Project in the 12/13th Five-year Plan of China —— Major New Drug Research &amp; Development Project</li> <li>People's Daily Health APP   The 13th China Health</li> </ul>		regions worldwide including Europe, the US, Canada, etc., covering global major and emerging markets

Annual Forum - Top Ten New Medicine

#### 汉达远<sup>®</sup>

汉达远® (adalimumab), the Company's first product indicated for the treatment of autoimmune diseases, was approved by the NMPA for the treatment of rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis in December 2020. It is the first China-developed adalimumab biosimilar that is manufactured in a China and Europe GMP certificated manufacturing site. The successful launch of 汉达远® has further expanded the patient population served by Henlius. As of April 2021, 汉达远<sup>®</sup> has been officially included in the NRDL. Tendering process has been finished in 24 provinces and municipalities. In April 2021, 汉达远 °'s sNDA for uveitis was approved by the NMPA.



Target

adalimumab

**Common Name** 

#### Indications

rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, and uveitis

#### Study Results

- Analytical study results published on The AAPS Journal
- Phase 1 clinical study results released at EULAR 2019
- Phase 3 clinical study results for psoriasis released at EADV 2020

#### Government Support



- National Science and Technology Major Project in the 12th Five-year Plan of China - Major New Drug Research & Development Project
- National Science and Technology Major Project in the 13th Five-year Plan of China - Major New Drug Research & Development Project

#### Patient Acces



- Adalimumab was recommended by guidelines for different autoimmune diseases with wide application worldwide
- The only adalimumab biosimilar evaluated in a Phase 3 clinical study among Chinese patients with Ps

#### **Commercial Partner**



Jiangsu Wanbang established the first whole-course care platform "Dayuan Home" for autoimmune patients in China, which fully integrates the functions of on-line hospital, popular science education, public assistance, medical insurance, patient management system, drug purchase map, and community care

#### Three Products Available for Commercialization in the Near Future

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HLX04 (bevacizumab), indicated for the treatment of colorectal cancer and nonsmall cell lung cancer, was accepted for NDA review by the NMPA in September 2020 and is expected to be approved for marketing in 2021. Different from currently approved bevacizumab biosimilars in China, the phase 3 study of HLX04 was conducted among Chinese patients with metastatic colorectal cancer, which helps to accumulate more clinical evidence and experience of bevacizumab in this patient population. Data from the Phase 3 study, which was presented at the 23rd annual conference of Chinese Society of Clinical Oncology (CSCO), showed that HLX04 is similar to the original bevacizumab in terms of efficacy, safety and immunogenicity. To reach a broader patient population, the Company also plans to initiate an application for an additional glioma (GBM) indication, a new indication added for the original bevacizumab, after HLX04 is launched. In addition to monotherapy, the HLX04 plus Serplulimab (anti-PD-1 mAb) is developed as one of the Company's key immunooncology combination therapies to treat various solid tumors.

### HLX01 (rituximab) is a product developed and manufactured by Henlius in response

to the differentiated development strategy of the marketed 汉利康® for rheumatoid arthritis indications (RA) for which the original rituximab has not vet been approved in China. The product has the advantages of low frequency of administration and long duration of drug effectiveness, which is expected to improve patients' medication compliance, effectively improve the quality of life of patients and reduce the medical burden of patients. In December 2020, the NDA for HLX01 (rituximab) for RA treatment was accepted by the NMPA, making HLX01 (rituximab) another important product in the field of autoimmune diseases of Henlius and thus further enriching the pipeline.

#### Serplulimab (anti-PD-1 mAb) is the core innovative monoclonal antibody product developed by Henlius, which can be used in combination with other products to develop immune combination therapy for the treatment of solid tumors. Henlius has built a forward-looking presence in the globalisation of Serplulimab, obtaining clinical trial approvals in China, the US, Poland and other EU countries.

In addition, the Company has focused on the selection of indications and combination therapies, with the clinical trials of two monotherapies and eight combination therapies (Serplulimab as backbone) underway in multiple countries and regions worldwide, covering major cancer types such as microsatellite instability-high (MSI-H) solid tumors, lung, hepatocellular, esophageal, head and neck, gastric cancers. Up to now, Serplulimab has enrolled about 2,000 patients in China, Turkey, Poland, Ukraine, Russia and other countries and regions, and is one of the PD-1 products with one of the largest international clinical data pools. In April 2021, the NDA of Serplulimab, for the treatment of unresectable or metastatic MSI-H solid tumors that fail to respond to the standard therapy, has been accepted by the NMPA and granted priority review status. Serplulimab is potentially to be the first anti-PD-1 mAb indicated for MSI-H solid tumors in China. For this indication, patients are screened by specific MSI-H tumor markers, rather than by different tumor types, with a wide range of patient population.

In addition, the NDA filing of Serplulimab in combination with chemotherapy for the first-line treatment of squamous nonsmall cell lung cancer (sqNSCLC) in China will also be expected in the second half of 2021, accelerating the development process of Serplulimab. Henlius has also reached a collaboration agreement with KG Bio in 2019, upon which KG Bio is granted exclusive rights to develop and commercialise Serplulimab in 10 Southeast Asian countries, thus laying the foundation for products to enter the international market.






### **Boosting Advanced Production**

To further promote the comprehensive development of the Company's commercialization and ensure high-quality production and stable supply of products, Henlius accelerated the scaling up of its commercialization capacity in 2020. By continuously introducing and applying international cutting-edge production technologies, the Company effectively controls production costs and improves production efficiency to create an advanced production platform with unique advantages.

#### Leading Manufacturing Technology

Continuous optimization and innovation of production technology is the key to ensuring high quality and affordability of biologics, and is also a driving force for the rapid development of China's biopharmaceutical industry. During the reporting period, Henlius continued to make efforts in the research and development of continuous manufacturing technology, application of single-use technology and localization of single-use consumables to further enhance production level and improve production efficiency.

Henlius actively promotes the research and development of continuous manufacturing technology and independently builds the continuous manufacturing platform for antibody drugs. During the reporting period, the Company successfully completed the construction, commissioning and validation of the pilot plant for continuous manufacturing, which covers upstream perfusion culture and downstream continuous production line, and has completed two batches of downstream continuous pilot production tests based on the existing project.

Henlius is also a pioneer in the use of sinlgeuse technology in China, especially singleuse bioreactors. It is estimated that the use of sinlge-use equipment not only reduces production costs, but also eliminates the efforts for clean-up and disinfection after each production cycle, which reduces perbatch production time and reduces the risk of contamination. In terms of supply chain localization, with a view to reducing dependence on international suppliers, Henlius has conducted comprehensive localization assessments of consumables, resins and production equipment. In addition to quality risk and technical assessment of suppliers, the Company has established an E&L (Extractable and Leachable) independent research platform, leveraging E&L experimental data to ensure the quality of supplied products meets the requirements and further reduce time and economic costs.

In addition, during the reporting period

Henlius actively developed its in-house media, and simultaneously achieved the goal of increasing titers and freely adjusting the ratio of N-Glycon. Henlius continued to improve titers and reduce costs while maintaining quality. The application of tangential flow filtration (TFF) and alternating tangential flow (ATF) filtration perfusion culture processes also help maintain high density cell growth in the reactor and significantly increase protein expression. The feasibility of production by domestic suppliers is now being evaluated to lead the upgrade of the domestic biopharmaceutical supply chain.

Henlius Achieves Milestones in Continuous Manufacturing Technology Development

Continuous manufacturing technology is the trend in the development of biopharmaceutical technology, which can improve the robustness and reliability of the production process, reduce production and fixed asset expenditures, and reduce plant construction time and the time required for product changeover in production. Continuous manufacturing technology is mainly implemented in upstream production through perfusion cell culture processes. In recent years, the gradual improvement of TFF and ATF technologies has allowed for a significant increase in cell density during upstream perfusion cell culture, resulting in a significant increase in antibody production titers.

Experimental data from Henlius shows that the cumulative titer of antibody production in perfusion cell culture can reach 40g/L, and the annual antibody production of a single 1,000L single-use bioreactor can exceed 300kg; while the titer of antibody production under fed-batch culture (fed-batch) conditions is about 5g/L, and the annual production of one 2,000L single-use bioreactor is about 100kg due to the titer limitation.

In the downstream production process, continuous manufacturing technology is realised mainly through the use of continuous flow chromatography, Process Analytical Technology and other technologies to integrate multiple process units, which can improve production efficiency and plant utilization while reducing the storage volume of intermediates, waiting time between steps, and the scale and corresponding investment required for instrumentation, thus achieving the goal of shortening production cycle time and reducing production costs.



#### Following the Highest Quality Standards

Since its incorporation, Henlius has always been committed to "quality", following the highest international quality standards and establishing a quality management system that meets the standards of China, the EU and the US. The system is expected to cover the entire life cycle from research and development to material management, product manufacturing, quality control, product supply management and particularly, product post-marketing surveillance.

### Certificated by International Authorities

Henlius strictly follows the laws and regulations involved in its operations, including the Drug Administration Law of the People's Republic of China, the Decision of the China Food and Drug Administration on Matters concerning Adjusting the Registration Administration of Imported Drugs, Good Manufacturing Practice for Pharmaceutical Products (amended in 2010), the Measures for the Administration of Drug Registration, and the Good Manufacturing Practice for Non-Clinical Laboratory Studies. Based on Chinese, US and EU GMP regulations, the Company has developed and implemented the Quality Policy Manual to clarify the overall GMP requirements for quality system and to refine the requirements in the Quality Policy Requirements (QPR) and Standard Operating Procedures (SOP) documents. To date, the Company's Xuhui Facility and accompanying quality management system have passed multiple on-site inspections and/or audits conducted by the NMPA, the European Medicines Agency, EU QP and international business partners, and have received GMP certifications from China and the EU.

Henlius Received EU GMP Certificate



On April 23, 2020, Henlius' drug substance (DS) line and drug product (DP) line for 汉 曲 优 <sup>®</sup> (trastuzumab) have successfully passed the European Union (EU) Good Manufacturing Practice (GMP) on-site inspection and the Company has received two EU GMP Certificates (Certificate of GMP Compliance of a Manufacturer) from Poland's Chief Pharmaceutical Inspector. As one of the most authoritative and rigorous inspections globally, EU GMP inspection is recognised by nearly 30 EU Member States, and the inspection results may also be shared with other countries that have signed Mutual Recognition Agreements (MRAs) with the EU, including the United States, Canada etc. Therefore, EU GMP Certificate is regarded as a "passport" for drugs to be launched in international market and has significant global impact.

With the EU GMP Certificates, Henlius' Xuhui Facility has become China's first EU certified GMP site to manufacture a self-developed antibody drug and 汉 曲 优 <sup>®</sup> is the first China-developed biosimilar that has passed the EU GMP inspection. This means that the Company has already built a commercial-scale manufacturing facility and a quality management system that are in line with the EU standards. This also means that China-developed antibody drug is breaking the GMP barriers to be launched on international market, laying a solid foundation for the Company to further expand its global footprints.

#### **Advanced Quality Management**

In order to improve quality management efficiency, Henlius adopts a paperless electronic system to manage processes and related documents in the quality management process, which shortens the information flow time while avoiding the possible loss of documents in the traditional process of transmission. On the one hand, the Company uses the TrackWise quality management system to track deviations and related corrective and preventive actions, and to follow up on issues that require validity review. On the other hand, it uses Documentum document management system to ensure proper document lifecycle management, version control, audit trail and other processes through consistent access to document content repositories. Together with enabling guick search, collaborative editing functions and automated workflows, the system can help improve efficiency and streamline the review and approval process. In addition, in response to the national strategy of "Made in China 2025" to build a strong manufacturing country, Henlius has taken the lead in launching a comprehensive information construction in OC labs, and has now completed the construction of a full set of information system and put it into commercial production use. The system not only provides a convenient way to query laboratory data, but also enables real-time data sharing with relevant departments,

which helps strengthen the monitoring and control in all aspects.

The Company set up a standard procedure to deal with rejected materials and products to regulate management of rejected raw materials, packing materials, drug substance and finished products. A special zone was made for rejected materials and products to effectively isolate them. A conspicuous sign is posted for people to identify the zone. The materials and products are properly stored and placed under control. When there are rejected materials or products, Global Quality Operations Department will have evaluation and decide the way to dispose of them. After the disposal plan is approved, the materials and products will be handled under the supervision of Global Quality Operations Department.

In addition, the Company regularly conducts quality audits and self-inspections to assess the effectiveness of its quality management system. During the reporting period, Henlius conducted 11 self-inspections within the Company, focusing on plant and utility facilities, quality assurance system, equipment validation and verification, warehouse and material management, quality control, computerised system, clinical production management, and production management. The inspection dimensions cover the 6 major parts of GMP - quality system, facilities and equipment, material, manufacturing, packing and labeling, laboratory control.

#### **Quality Culture Building**

Quality culture is an important part rooted in the corporate culture of Henlius. The Company has made May 16, the day when the first prescription of 汉利康 ® was issued, as the Quality Culture Day of Henlius, advocating that all employees, regardless of their positions, should strive for continuous improvement of quality in the whole product lifecycle. At the same time, the Company has incorporated basic GMP training into the mandatory orientation course for new employees, and has included a wide range of quality training in its annual training programme. The UL training management system, ComplianceWire®, is also introduced to advance the information technology application in quality management system. Project leaders can create on-line quizzes in the system and distribute them to project team members, and employees can complete self-study and take exams at any time.

During the reporting period, Henlius conducted a total of 82,945 hours of quality training and provided quality training for 733 people, with the average number of quality training hours per captia reaching 113.16.



EU aseptic GMP key points analysis and experience sharing for inspection



Aseptic pharmaceutical enterprise control system construction and insights



China's medical device business laws and regulations system and key inspection practice interpretation



Microbiology basic knowledge training



EU GMP regulations, PIC/S training



EU GMP regulations, PIC/S training

## **Ensuring the Safety of Drug Use**

#### **Clinical Drug Use Safety**

Henlius is committed to ensuring the safety of subjects in the every stage of drug administration. In clinical trials, the Company conducts strict screening of subject enrollment and partner institutions respectively. For subject enrollment, the Company follows the SOP of "Subject Eligibility and Trial Selection" to check and screen subjects, and protects subject privacy by withholding their personal information during the whole communication projects management team arranges personnel to conduct research in hospitals qualified for clinical trials after project training, and selects qualified hospitals and investigators with active willingness to participate as well as sufficient potential subject pool to join the clinical trials.

Also, the Company has set up a "pre-warning" mechanism based on the first principle that "clinical trials are not trivial and the rights and interests of subjects are protected". Henlius has purchased the relevant "clinical trial insurance" for each participant in the clinical trial, which is effective immediately upon the successful entry of subject into the trial. During the course of the clinical trial, the Company will ensure that the subjects

will receive the corresponding claims in a timely manner if the costs are incurred due to adverse events or serious adverse events, so as to protect the rights and interests of the subjects to the maximum extent.

In addition, Henlius conducts real-time and regular signal detection and management according to a drug signal management system. If a new safety risk arises for a Henlius product, corresponding risk mitigation measures will be taken, such as updating clinical trial protocols, investigator manuals, informed consent forms and drug instructions.



#### **Post-marketing Drug Safety**

After the drugs are marketed, Henlius will comprehensively collect adverse events, promptly evaluate and submit adverse reaction reports to regulatory authorities, monitor drug safety signals, assess drug risks, and take appropriate risk mitigation measures to ensure patient drug safety to the maximum extent. The Company established and implemented the Allstaff Adverse Event Reporting, Adverse Event Monitoring, Adverse Event Collecting, Handling and Reporting, Periodic Safety Summary Report, Risk Management Plan and Risk Control Plan and other systems. In addition, Henlius has established the Global Drug Safety Committee (GDSC) and the Benefit-Risk Council (BRC) to identify, evaluate and communicate risks related to product safety and take risk mitigation measures when appropriate, thus establishing a more robust pharmacovigilance system. In March 2021, Henlius was awarded as the "Outstanding enterprise for the evaluation of ADR Monitoring in 2020" by the National Center for ADR Monitoring, NMPA, becoming the only pharmaceutical company in Shanghai to receive this award.

Henlius strictly implements the *All-staff Adverse Event Reporting*, and collects adverse event reports as comprehensively as possible through email, 24-hour hotline, fax, and other channels. The Company regularly conducts training on the "All Employee Adverse Event Reporting" for all employees, and adds this training to new employee orientation, so that all employees could understand that "everyone is responsible for reporting safety information on Henlius products," and that relevant safety information is reported to regulatory authorities in a timely manner.

Proactive, positive and rapid response to recalls is also a reflection of the Company's social responsibility. In order to ensure that all relevant departments of the Company can respond promptly when a recall occurs, Henlius has formulated a standard procedure for recalled product management with reference to the requirements of laws and regulations such as the Measures for Management of Drug Recall, the Good Manufacturing Practice for Pharmaceutical Products (amended in 2010) and the European Union Guide to Good Manufacturing Practice for Medicinal Products. The Company also regularly conducts product recall simulations to systematically verify the effectiveness of the existing recall system.

During the reporting period, Henlius continued to carry out pharmacovigilance activities and take risk mitigation measures, and maintained a good benefit-to-risk ratio for each marketed product to ensure drug safety.



#### 2020 All-staff Adverse Event Policy Training



During the reporting period, the Company provided training to all employees on the adverse event reporting policy so that each employee understands the sources of product safety information, the content, time frame and manner of reporting. The Company requires employees to report product safety information related to Henlius's marketed products to Pharmacovigilance Department within 24 hours.



# FOSTERING WIN-WIN COLLABORATION WITH HONESTY AND RELIABILITY

Henlius attaches importance to the power of industry cooperation, constantly improving the management and cooperation of upstream and downstream suppliers in the industry chain to empower the development of the industry chain; in addition, the Company also actively participates in technical cooperation and standard building to promote the healthy development of the pharmaceutical industry. Together with global business partners, the Company will continue to expand international footprint with more products and bring high-quality treatment options to more patients worldwide.



## **Forging Responsible Supply Chains**



Henlius has formulated and implemented the Supplier Management Regulations to clarify the qualification of suppliers, principles of selection, quality assessment methods, evaluation criteria, and procedural requirements for material supplier approval to ensure the objectivity, fairness and effectiveness of supplier selection, assessment, approval and withdrawal. At the same time, it clarifies the responsibilities of each department in the business department, supply chain department, warehouse, quality assurance department and quality control department to regulate supplier management behavior and ensure the quality and safety of products and services.

After implementing a strict supplier access process, Henlius classifies suppliers into A, B and C categories based on supplier level and material level. For Class A material suppliers, the Company requires the signing of a quality agreement *Establishment and Requirements of Quality Assurance Agreement*. In addition, according to different categories, the Company has targeted different written audit, qualification audit and on-site audit plans.

In order to ensure that the concept of environmental protection is practiced from the source, Henlius has established EHS audit management policies and processes for suppliers. EHS audits are conducted after risk assessment of direct material (such as raw materials, auxiliary materials, packaging materials, etc.) producers. The performance of suppliers in terms of environmental protection is assessed comprehensively through both written and on-site audits. For the suppliers who fail the audit, the Company requires them to rectify and submit the rectification results within three months. If they still fail, the qualified supplier status will be withdrawn.

The Company divides the suppliers for procurement into direct material procurement and indirect material (such as process gases, high efficiency filters, clean control areas, etc.) procurement suppliers, as follows.



Number of suppliers by country/region	2020	
Eastern China	126	
Southern China	1	
Central China	1	
Northern China	8	
Southwest China	1	
Northeast China	1	
Overseas	2	
Total	140	

During the reporting period, the Company analyzed the GMP material categories based on the three dimensions of procurement amount, supply risk, and technical and regulatory feasibility, and formulated a phased localization process. Among them, the Company focused on the procurement of key materials such as single-use consumables, filters, virus removal film packs and culture media, and set up a time schedule for material localization and multi-channel procurement to carry out localization supply chain work in a planned and prepared manner. In 2020, in order to control procurement and supply risks and enhance business continuity, the Company has improved its business continuity while achieving cost reduction and efficiency increase through localization and increasing supply channels.

Henlius pays attention to the communication with suppliers and understands the demands of both sides through regular communication and occasional visits to achieve mutual benefit and win-win success.

# d Strategic Supplie

#### Henlius and Strategic Suppliers Have Regular Meetings and High-level Visits

Cytiva is an important strategic supplier of Henlius. Before the pandemic outbreak, the Company maintained communication with Cytiva through bi-weekly meetings to confirm the supply and payment status. After the outbreak, in order to ensure the sustainable supply of consumables and fillers during the pandemic and confirm the follow-up solutions in advance, Henlius changed the frequency of communication to once a week to ensure good communication via on-line platform and timely feedback from both parties.

### 2000 JJ

Henlius Cooperates with Banks to Provide Financial Support to Suppliers

During the reporting period, Henlius actively helped its supplier partners who were in the growth stage by cooperating with banks and using its good corporate credit and contracts with suppliers as endorsements to help partner enterprises obtain loans at low interest rates. After signing the Reverse Factoring Cooperation Agreement with banks, the banks reverse factored the accounts receivable of upstream enterprises and provided reverse factoring financing lines. The line of credit is used for the bank to provide factoring financing directly to the upstream company, and the repayment source of the upstream company is the payment from Henlius to the supplier.

## **Carrying Out Technical Cooperation**

In the process of technical cooperation with partners, Henlius gives full play to its advantages and helps build an industrial ecosystem, striving to become a reliable partner, an innovation enabler and a contributor to the global health industry.

Exploring Continuous Manufacturing Technology with Cytiva to Promote Innovation in Biologics Manufacturing Technology Upgrades

On July 31, 2020, a seminar forum on digital manufacturing of biopharmaceuticals was held in Songjiang District, Shanghai, hosted by Shanghai Association of Food and Drug Safety and organised by Henlius and Cytiva, where technical experts, policy experts and enterprise representatives from the biopharmaceutical industry gathered to discuss the future of digital manufacturing of biopharmaceuticals. During the forum, Henlius and Cytiva reached a strategic cooperation on the development of continuous manufacturing at Henlius' Songjiang Facility, and jointly build a continuous manufacturing upstream and downstream technology platform.

On the upstream side, Henlius and Cytiva plan to collaborate on perfusion process development and conduct experiments around multiple perfusion modes to identify the most suitable and cost-effective upstream perfusion production mode for Henlius' related products and to help Cytiva determine parametres related to higher cell density cell perfusion culture; on the downstream side, the two companies plan to collaborate on an ultra-fast chromatography technology to evaluate the feasibility, scaling-up and future economic benefits of this new technology at the laboratory and pilot levels.

As a pioneer of innovative biopharmaceutical manufacturing technology in China, Henlius will continue to work with Cytiva to explore the international frontiers of biopharmaceutical manufacturing, such as continuous manufacturing technology, to blaze a trail for digital manufacturing of biopharmaceuticals in China, and to help Chinese biopharmaceuticals continue to move towards the goal of achieving digital manufacturing.



### **Expanding Business Topology**



With the initial goal of "Reliable Quality, Affordable Innovation", Henlius is actively working with global partners to accelerate the full penetration of biologics in major and emerging markets, aiming to bring quality biologics to patients worldwide.

In 2020, 汉曲优<sup>®</sup> (trastuzumab, Zercepac<sup>®</sup> in the EU) by Henlius was approved in both China and the EU, becoming the first Chinese monoclonal antibody biosimilar certificated by the EU GMP. With the launch of 汉 曲 优 <sup>®</sup>, Henlius, together with its commercial partner Accord, is actively promoting the commercialization of 汉曲优<sup>®</sup> in the EU to achieve a robust penetration in overseas markets. Headquartered in the United Kingdom, Accord is one of Europe's fastest growing pharmaceutical companies, with broad market coverage that holds a leading position among European generic and biosimilar companies and a marketing and distribution network that reaches more than 80 countries worldwide. As early as 2018, Henlius has already laid out the commercialization market of 汉 曲 优<sup>®</sup> in Europe in a forward-looking manner and granted Accord exclusive commercialization rights of 汉曲优® in 53 countries in Europe, including the UK and France, and 17 countries in the Middle East and North Africa, including Saudi Arabia and the United Arab Emirates, and some Commonwealth of Independent

States (CIS) countries. During the reporting period, the Company upgraded its cooperation with Accord. Pursuant to the cooperation, Accord was granted licenses for new dosage forms of 汉 曲 优<sup>®</sup>.Since its approval in the EU, the high quality of 汉曲优<sup>®</sup> has been recognised internationally and has been successfully marketed in nearly 20 EU countries and regions, including Germany, Spain, France, Ireland, Italy, Hungary, etc. It has also entered National Health System and many top hospitals in the UK, including Chelsea Hospital, Westminster and Kings College Hospital in London, etc. In addition, during the reporting period, Henlius entered into a partnership with Mabxience, a global biotechnology company, granting Mabxience exclusive rights to develop and commercialise 汉曲优<sup>®</sup> in oncology therapeutics in Argentina, Uruguay and Paraguay. After the approval of 汉 曲 优<sup>®</sup>, the Company further entered into a partnership with Accord US, granting Accord US exclusive rights to develop and commercialise 汉曲优® in the US and Canada, thus successfully expanding the commercialisation of 汉曲优® to the biologics market in major and emerging markets.

During the reporting period, Henlius joint force with Essex to co-develop its HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) indicated for ophthalmic diseases such as wet agerelated macular degeneration (wAMD) and to grant an exclusive license to Essex to develop, manufacture and commercialise HLX04-O in the field of human ophthalmic therapies globally. Henlius and Essex will speed up the global multi-centre clinical trials of HLX04-O in countries and regions such as China, Australia, the EU, the US, etc. and apply marketing authorisation in different countries and regions around the globe based on the research results. So far, the filing of clinical trial for HLX04-O has been approved in Australia, the US and European countries such as Latvia. The multi-centre Phase 3 clinical study of the project is intended to be initiated in the near future.



**HLX04-O clinical trials approved** 

in Australia, the US and European countries such as Latvia

#### **Expanding Business Topology**



#### **Pursing Strategic Cooperation to Establish Global Presence**



Hong Kong, Macau, China

### **Promoting Industry Development**

Henlius attaches great importance to scientific innovation and technical talent development. The Company actively conducts research and delivers training and is committed to building a communication platform for exchanges and cooperation in the biopharmaceutical industry. At the same time, as a leading biopharmaceutical company in China, the Company actively plays a leading role in the industry and works together with industry partners to improve the development of biopharmaceuticals in China and promote the sound development of China's biopharmaceutical industry by integrating industry technology resources. • High-end research training for young and middle-aged physicians nationwide in collaboration with *NEJM Frontiers of Medicine* 

Through this training, outstanding young and middle-aged physicians from a total of more than 40 hospitals across China were helped to improve their academic writing and research skills in all aspects, expanding the influence of China's original first-class research results, and promoting the development of cutting-edge theories.

• School-enterprise cooperation with East China University of Science and Technology and China Pharmaceutical University

Relying on the scientific research advantages of the partner universities and Henlius' own strong R&D strength to establish a joint practice base, the Company provided a cooperation platform for in-depth industry-academia research between schools and enterprises to further enhance the Company's innovation ability and scientific research strength, as well as to continuously provide R&D and manufacturing talents for the Company.

• Led the initiation and compiling of China's first biosimilar science book



#### Henlius was Approved to Establish a Postdoctoral Research Station



In November 2020, Henlius was awarded the "Postdoctoral Program in Pudong New Area" and approved to set up a branch station of Enterprise Postdoctoral Research Base, speaking volumes about the high-level research team and research capability of Henlius. Since then, the postdoctoral research station will become an important part of the Company's innovative R&D and talent cultivation.

The approval of the establishment of the postdoctoral research workstation is of great significance to Henlius to improve its independent innovation capability and accelerate the transformation of scientific and technological achievements. On the one hand, the postdoctoral research station will serve as an important platform for introducing and training high-caliber talent and an incubator for training young senior technical and management talent. On the other hand, the postdoctoral research station is also an important bridge to strengthen exchanges and cooperation with top universities and research institutions. According to the cooperation mechanism between postdoctoral research stations and mobile stations, Henlius will collaborate with universities and scientific research institutions to recruit and train postdoctoral staff, and provide postdoctoral staff with more research topics and opportunities that are relevant to the industry. The Company will give full play to the postdoctoral research performance in technology research, process improvement and industrial application, thus promoting the combination of production, learning and research, and cultivating senior scientific and managerial talent to meet the needs of national economy and enterprise development. The Pudong New Area government will also provide certain financial support for the postdoctoral training of Henlius.

#### Henlius Led the Initiation and Compiling of China's First Biosimilar Science Book

gradually become a hot spot for research and development in the pharmaceutical industry both at home and abroad. In order to lighten the burden of public countries and regions have encouraged application of biosimilars through different policies and approaches. To further promote the development of biosimilars in China. The book consists of ten chapters on biosimilar overview, and evaluation, manufacturing and quality control, review and approval, pharmacovigilance, market access, clinical practice and post-marketing and attention of pharmaceutical companies, healthcare professionals, payers, patients, and the public to biosimilars, thereby enhancing the accessibility of biosimilars. The project veterans in the field of biosimilar manufacturing to form an editorial review committee and a team of nearly 50 writers.

# NURTURING TALENT TO SEEK COMMON DEVELOPMENT

Talent is the most valuable asset of the Company and the driving force for long-term development. Henlius always adheres to the value of "people-oriented", upholds the concept of "attracting people with ideas, uniting people with results, cultivating people with work, and assessing people with performance". The Company makes great efforts in attracting, cultivating and retaining talents, putting right people to right place.



### **Employment in Compliance with Law**





Henlius strictly abides by the Labor Law of the People's Republic of China, the Labor Contract Law of the People's Republic of China, the Social Insurance Law of the People's Republic of China and other laws and regulations, and formulates and constantly improves the employee management policies such as the Henlius Employee Handbook and the Henlius Compensation and Welfare Policy. The Company resolutely refrains from employing child labour and forced labour, and from discrimination caused by different geographies, genders and ethnicities. During the reporting period, there were no incidents of child labour and forced labour in the Company.

Henlius has been expanding its recruitment channels, including online recruitment, offline recruitment and internal recruitment, to attract more high-quality talent. As of December 31, 2020, the Company had 1,873 employees, an increase of 59.81% over 2019. During the reporting period, the Company's employee turnover rate was 13.19%.





### **Caring for Employees**

#### Compensation and Benefits System

Remuneration	Benefits	Activities	
Basic salary	Monthly allowance	Team building and annual dinner	
Service bonus	Statutory and		
Performance bonus	supplementary annual leave	<ul> <li>Monthly birthday party</li> </ul>	
Excellent staff awards	Paid sick leave	Sports events (running,	
(Blue Angel, Star of the Ouarter)	Insurance and housing fund	badminton, table tennis, archery, etc.)	
Quarter)	Supplementary medical /	Trade union activities	
Equity incentive plan	healthcare insurance	•	
	<ul> <li>Supplementary provident fund</li> </ul>	Family day	
	Annual medical test		
	Festival gifts		

#### **Employee Benefits**

Henlius understands that talent is the core resources of an enterprise and is grateful for the hard work of its employees. To provide basic rights and benefits such as social security, housing fund and statutory annual leave, the Company offers employees with additional benefits such as special annual leave, supplementary housing fund and flexible work policy.

Henlius respects and cares for its female employees. The Company prepares warm gifts for female employees on International Women's Day. In 2020, Henlius set up a "Maternity Room" in the Company to provide a place for breastfeeding employees. On Children's Day, the labour union also prepares holiday gifts for the "second generation of Henliuser".

In addition, the Company encourages female employees to focus on self-development. In 2020, the Company's labour union, along with the Fosun Inernational labour union and the Fosun Pharma labour union, organized a training course on "Awaken Your Feminine Energy" to encourage female employees to grow with the Company.

#### **Employee Activities**

Henlius is committed to providing a comfortable working environment and a relaxing working atmosphere for its employees, and constantly enriching their lives by holding a variety of employee activities. Henlius Monthly Employee Birthday Party



Henlius holds monthly birthday parties for employees whose birthdays fall in that month as a tradition. Upon different festivals, the Company's Administration Department plans different themes for the birthday parties and arranges a variety of DIY activities related to the themes (such as handwritten fortune characters, DIY rattles, succulent plants and DIY octavo boxes, etc.). These activities can bring employees a sense of belonging, improve employee engagement, and provide an informal platform for cross-functional communication.

#### **Employee Communication**

Maintaining good communication with employees is an important foundation for efficient management of the Company. By setting up a perfect communication system, Henlius provides a channel for colleagues from different departments, positions and ranks to upload and disseminate information. The Company encourages employees to give feedback on problems in the system and process through emails, phone calls and face-toface meetings, so as to effectively understand employee needs and solve their practical difficulties, and ensure that employees work and learn in a relaxed and pleasant environment.

To understand employee satisfaction with corporate governance and operational management, Henlius conducts annual employee satisfaction surveys, and each functional department conducts regular internal satisfaction surveys to further improve internal management. Henlius regards employee effectiveness as a core component of organisational effectiveness and one of the key indicators of a high-performing organisation. During the reporting period, the Company conducted employee surveys on two core indicators of employee effectiveness - employee engagement and organisational support - with an overall response rate of 99%. The results show that the Company respectively scored

84 and 83 points in employee engagement and organisational support. The scores on the Company's mission, vision and strategy reflect the employees' recognition and expectation of the Company's development, while the Company also identifies findings to be improved in working procedures and responsibility division.

Based on the research findings, the Company has quickly launched an optimization action plan, set up a cross-functional working procedure optimization task force group, and promoted process improvement and efficiency enhancement at the company level.





#### **Employee Safety**

Henlius cares about the physical and mental health of every employee and ensures a green and safe office environment for them. By establishing and improving the EHS management system and formulating and implementing the Environment, Health and Safety Management Manual, Occupational Health Management Regulations, Special Equipment Management Procedures and Hazardous Work Control Procedures, the Company standardises its safety management and improves employees' safety awareness.

The EHS Department of the Company formulated a yearly training plan covering various fields of environment, health and safety in early 2020 and delivered training on more than 10 types of topics according to the plan. With the help of platforms such as online meeting platform and online learning system "Henlius University", the Company raises employees' safety awareness and sharpens their risk response ability in all aspects. During the reporting period, the Company provided EHS training to 8,717 people with a total of 43,507 training hours.

In addition, the Company provides "3 Levels" of safety education to new employees and establishes registration cards for 3-level safety education and training. To further enhance employee ability to resist risks and improve their self-help ability, the EHS department organised several fire drills, Level 2 biosafety laboratory drills, environmental emergency response plan drills and special equipment safety incident drills respectively at Xuhui Office and Songjiang Office during the reporting period, and carried out abundant safety education activities during the Production Safety Month and EHS Management Month. During the reporting period, the Company conducted emergency drills on a regular basis, formulated emergency drill plans and provided opportunities for nearly 1,835 people to participate in drills and related training.

During the reporting period, the Company's safety drill coverage rate was 100%. There was no employee death due to work-related accidents, and there were 5 traffic safety accidents during employees' commuting road trips, with an injury rate of 1.75 per million working hours. After the incident, Henlius has provided safety education to employees to improve their traffic safety awareness.





total of

43,507 training hours

Building a Green Enterprise by Guarding the Safety line | 2020 Production Safety Month



As a biopharmaceutical company, Henlius has long attached great importance to EHS management and has made environmental safety and health an important part of its corporate culture values.

The EHS Department has introduced a series of activities into this year's production safety month, fully mobilizing all employees and striving to make the awareness of production safety and environmental protection sink into the mind of every Henlius employee. The Company has also organised safety production training and environmental management training, encouraging all departments to actively selfexamine and improve employees' safety awareness as a whole. In addition, the Company has organised the viewing of safety production education films and micro movies and actively carried out activities such as EHS safety knowledge quiz and VR immersive safety scene experience. It is hoped that the above can consolidate and strengthen employee safety awareness, comprehensively cover employees of different positions and functions, and realise the effect of activities with full participation.

The VR immersive safety scene experience introduced in this production safety month optimises the traditional form of conducting experiential safety education, enabling the experiencing personnel to integrate into the accident environment and feel the serious consequences brought about by irregular operations, essentially enhancing people's vigilance, and effectively establishing the red line awareness of construction safety.

### **Employee Training and Development**

Talent development is essential to driving the Company's rapid development and keeping the momentum for growth. By continuously improving the staff training system, Henlius has formulated and continuously optimised the Staff Training Management System, actively encouraged learning and communication among employees, and continuously improved the professional quality and workplace skills of employees.

#### **Employee Training**

To enable employees to quickly integrate into the company and master the job skills of their positions, Henlius provides systematic training for employees, including professional course training, general course training, leadership training and customised training. In addition, the Company has established a comprehensive and diversified training system, which is divided into three categories: regular programmes, special categories and training for new graduates. Each major category is further subdivided into various subcategories, aiming to make learning and improvement opportunities cover employees at all levels.

At the beginning of 2020, the Human Resources Department of the Company formulated a training plan for the whole year according to the needs of employees in each department and at each level. Through rich course learning and project training, supplemented by diversified formats, the training attracts more interactive participation from employees and nonprogramme participants. The Company's internal training team accelerates the development of training courses and uses the E-learning platform combined with visual posters for promotion. Learning Express is launched on a monthly basis to report the status and feedback of monthly training courses and to clearly show the online learning landscape of employees in each department.



### E-learning "Henlius University" Online Learning Platform

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On February 11, 2020, "Henlius University" E-learning platform was officially launched to implement departmental community management and become a tool and sharing platform for continuous learning in all departments. Since then, the learning of Henlius employees is no longer restricted by time and geography, and the training process and management of the company is more systematic. During the reporting period, E-Learning assisted employees in completing 172 internal courses and 169 external courses, with a total of 5,056 person-times on the platform. In addition, during the reporting period, "Henlius University" cooperated with various departments such as sales, quality, legal and medical departments to conduct various knowledge competitions, special knowledge seminars and tests.

During the reporting period, the Human Resources Department of Henlius provided training for 1,530 employees\*, which accounted for 81.69% of the total number of employees. Employees were trained for a total of 32,976 hours. The average training hours per capita was 17.61 hours.

In addition, Henlius has created training courses for its employees under the "Hong", "Lin" and "Target" programmes, taking into account its own business practice.

The "Lin" programme aims to deepen employees' understanding of the strategy and organisation of Henlius, clarify the business and talent needs of the department, identify the gap between the current situation of talent and future business development needs, and make strategic planning and preparation for future business development and talent development. The "Target" program is a learning program for leadership development at Henlius. The programme meets the development needs of middle management talent, aims to enhance managers' self-awareness and organisational awareness, and improves the leadership ability of middle managers.

#### Staff development

Henlius continues to improve its employee promotion system and helps employees

complete their annual career planning and customise their individual development planning based on annual talent review and performance review. In 2020, Henlius held a total of 25 talent review meetings, covering about 250 key positions in 14 departments of the company. According to result of talent review, the Company identified 500 core positions in 2021, including approximately 100 key positions at the company level, accounting for about 20% of the total. In addition, based on this talent review, Henlius has formulated a talent development plan for managerlevel, director-level and high-potentials.



\*Data of EHS training, legal compliance and anti-corruption training, and quality training provided to employees are presented in the corresponding sections of the report and are not included in the training data provided by the Human Resources Department.

# ENVIRONMENTAL PROTECTION AND GREEN OPERATIONS

Henlius takes "preventing environmental pollution and reducing energy consumption" as its environmental management policy, and continues to explore and apply new technologies to prevent pollution, actively promote energy saving and emission reduction, and reduce the negative impact of business operations on the environment. The Company focuses on improving environmental management, improving environmental protection system, optimizing environmental protection measures, and striving for green development.



## **Abiding by Green Production**

Henlius strictly complies with the Air Pollution Prevention and Control Law of the People's Republic of China, the Water Pollution Prevention and Control Law of the People's Republic of China, and other laws and regulations of the place of operation, and has established a series of environmental protection systems, management systems and organisational guarantee mechanisms, including the Waste Gas Management Regulations, Waste Water Discharge Management Regulations, Solid Waste Management Regulations and other systems, in order to improve the level of environmental protection compliance, reduce waste of resources and bring down pollution emissions.

In order to improve the level of corporate environmental management, Henlius has established a sound environmental management system and formulated *a*  Pollution Prevention and Control Responsibility System, and EHS representatives regularly report to Henlius management on EHS operations, including environmental protection. Henlius carries out environmental protection management with a top-down management system.

During the reporting period, the Company provided a total of 43,507 hours of EHS training to 8,717 employees.



EHS Management Model of Henlius

#### **Energy Management**

The main energy sources include purchased electricity and natural gas. In order to save energy and reduce carbon footprint, the Company is committed to continuously improving energy use efficiency through process optimization and other measures. During the reporting period, the EHS Department launched a clean production project to assess the Company's existing energy use and propose a reasonable improvement plan accordingly. Through

strict energy control work, the Company achieved a decrease in energy consumption despite the fact that its manufacturing capacity was doubled in 2020.

During the reporting period, the comprehensive energy consumption intensity of Henlius was 2.89 GJ/ RMB 10,000 of revenue, a decrease of 66.44% compared with 2019, and the total greenhouse gas emission intensity was 0.33 tons of CO<sub>2</sub>/ RMB 10,000 of revenue.



#### 2020 Comprehensive energy consumption intensity

GJ/ RMB 10,000 of 2.89 revenue

#### Compared with 2019

66.44%

Indicator	Unit	2018	2019	2020
Purchased electricity	kWh	9,061,100	10,438,200	20,089,862
Natural gas	Cubic metre	1,583,072	1,057,926	2,559,789.50
Owned vehicle gasoline usage	Litre	/	13,945.06	0
Direct energy consumption	CJ	60,282.97	40,721.30	97,476.12
Indirect energy consumption	ſIJ	32,619.96	37,577.52	72,323.50
Comprehensive energy consumption	ſIJ	92,902.93	78,298.82	169,799.62
Comprehensive energy consumption intensity	GJ/RMB 10,000 of revenue	125.19	8.61	2.89
Scope 1 greenhouse gas emissions <sup>*1</sup>	Tons of CO <sub>2</sub>	3,427.13	2,328.02	5,534.75
Scope 2 greenhouse gas emissions* <sup>2</sup>	Tons of CO <sub>2</sub>	6,168.49	7,105.98	14,133.21
Total greenhouse gas emissions	Tons of CO <sub>2</sub>	9,595.62	9,434	19,667.96
Total greenhouse gas emission intensity* <sup>3</sup>	Tons of CO <sub>2</sub> / RMB 10,000 of revenue	12.93	1.04	0.33





Trends in Greenhouse Gas Emissions from 2018 to 2020



Total greenhouse gas emission intensity

[1] Mainly greenhouse gases from owned vehicle gasoline usage and natural gas.

[2] Mainly greenhouse gas from purchased electricity used.

[3] The Company began commercialisation of 汉利康<sup>®</sup> (rituximab) in China in May 2019. Prior to that, the Company did not commercialise any products and therefore did not generate revenue from sales of products, so the greenhouse gas emission intensity was more volatile compared with the data in late stage.





2020 Water consumption intensity



**Decrease compared with 2019** 

66.53%

Water Consumption from 2018-2020

#### **Water Resource Management**

Henlius uses water from municipal water. In order to further reduce industrial water consumption, during the reporting period, the Company launched water reuse projects, and water reuse projects were constructed and put into use at Songjiang and Xuhui Facility respectively. The water from the circulating cooling tower and the concentrated water from the pure water preparation are treated in the water reuse facilities and then reused for water reuse in the circulating water tower. Among them, Songjiang Facility reused 48,717.93 tons of water in 2020; the water reuse project of Xuhui Facility was completed in October 2020, and the amount of water reuse within 45 days of operation is estimated to be about 3,847.50 tons\*1.

During the reporting period, the total water consumption of Henlius was 233,594 cubic metres, with a water consumption intensity of 3.98 cubic metres / RMB 10,000 of revenue, seeing a decrease of 66.53% compared with 2019.

#### **Packaging Material Management**

The packaging materials of Henlius are mainly used in the manufacturing, transportation, sales and storage of products. By formulating and continuously optimising the material management system, the Company actively reduces the use of packaging materials and improves the utilization rate of packaging materials in the process of product packaging source design, product production process and material transportation.

During the reporting period, the packaging material consumption intensity was 0. 73 KG/ RMB 10,000 of revenue, a decrease of 14.54% compared with 2019.

Indicator 2018 2019 2020 Unit Total water 88,141 108,013 233,594 Cubic metres consumption Water Cubic metres / RMB consumption 118.77 11.88 3.98 10,000 of revenue intensity\*2



#### 2020 Packaging material consumption intensity 0.73 KG / RMB 10,000 of revenue

#### Decrease compared with 2019



#### The Packaging Materials Use from 2019-2020

Amount of packaging materials used	Unit	2019	2020
Inner packaging materials	Ton	/	13.03
Outer packaging materials	Ton	/	29.99
Total packaging materials	Ton	7.79	43.02
Packaging material consumption intensity	KG / RMB 10,000 of revenue	0.86	0.73

[1] Xuhui Facility's reuse water amount is the estimated amount.

[2] The Company began commercialisation of 汉利康<sup>®</sup> (rituximab) in China in May 2019. Prior to that, the Company did not commercialise any products and therefore did not generate revenue from sales of products, so the water consumption intensity was more volatile compared with the data in late stage.



#### **Pollutant Discharge Management**

Henlius strictly complies with the laws and regulations related to pollutant emissions in the places where it operates and has established corresponding management systems. The Company implements quarterly monitoring work in strict accordance with the environmental monitoring programme formulated at the beginning of each year, and takes preventive and control measures for pollutant emissions of wastewater and exhaust gas to ensure stable and compliant emissions of pollutants.

The exhaust gas pollutants come from the volatilisation of chemical reagents, acids and bases and organic reagents used in the production and inspection process. Henlius strictly complies with the Emission Standards for Air Pollutants in Pharmaceutical Industry (GB37823-2019), Shanghai Emission Standards for Pollutants in Biopharmaceutical Industry (DB31/373-2010), Comprehensive Emission Standards for Air Pollutants (DB31/933-2015), Emission Standards for Odor (Odor) Pollutants (DB31/1025- 2016), Emission Standards for Boiler Air Pollutants (DB31/387-2018) and other laws, regulations and industry standards, to develop and continuously optimise the Company's Exhaust Gas Management Protocol, through the installation of fume hood work facilities, the use of exhaust ducts and roof exhaust fans, the unified collection of exhaust gas, through the activated carbon adsorption to meet the standards and then released into the atmosphere.

The main wastewater pollutants involved in the Company's business are chemical oxygen demand (COD), ammonia nitrogen ( $NH_3$ -N) and total phosphorus and total nitrogen in various types of wastewater. The Company strictly complies with Shanghai Biopharmaceutical Industry Pollutant Discharge Standard (DB31/373-2010) and Shanghai Comprehensive Sewage Discharge Standard (DB31/199-2018), and formulates the Wastewater Discharge Management Regulations to clarify the management process of wastewater discharge by combining with the operational characteristics of pharmaceutical enterprises themselves. The discharge of industrial wastewater generated by the Company is treated by the wastewater pretreatment device to meet the standard.

Due to the scaling up of manufacturing capacity, the pollutant emissions of Henlius rose during the reporting period compared with 2019, with details of the emissions as follows.

Indicator	Unit	2018	2019	2020
Exhaust gas				
Nitrogen oxides	Ton	1.01	0.61	0.30
Sulfur dioxide	Ton	0.05	0.05	0.03
Total non-methane hydrocarbons	Ton	0.02	0.02	0.03
Wastewater				
Chemical oxygen demand (COD)	Ton	0.12	0.22	0.64
Ammonia nitrogen (NH <sub>3</sub> -N)	Ton	0.01	0.01	0.01
Total wastewater discharge	Ton	1,134	2,229	11,285.70

#### Pollutant Emissions in 2018-2020

#### **Waste Management**

Henlius strictly complies with the Pollution Control Standards for General Industrial Solid Waste Storage and Disposal Sites (GB18599-2001), Pollution Control Standards for Hazardous Waste Storage (GB18597-2001) and Technical Specification for Hazardous Waste Collection, Storage and Transportation (HJ2025-2012), collects general waste and hazardous waste separately, and formulates Solid Waste Management Regulations, and Hazardous Waste Management Regulations, etc. to clarify waste management measures.

For solid wastes like activated sludge and domestic waste, Henlius adopts the compliance method of recycling and treatment by the park, safe disposal or entrusting them to the health department. For hazardous wastes, such as waste culture bags and waste filters, Henlius adopts the management ledger and transfer coupon system according to relevant laws and regulations, and regularly entrusts relevant qualified organisations to safely dispose of them. The Company continuously updates the *Hazardous Waste Management Regulations* to standardise the types of hazardous waste in each department and ensure comprehensive collection and disposal of hazardous waste.

During the reporting period, the solid waste emissions of Henlius were 598.18 tons, and the solid waste emission intensity was 10.18 KG / RMB 10,000 of revenue, seeing a decrease of 68.64% in emission intensity compared with 2019.

Indicator	Unit	2018	2019	2020
Total domestic waste*1	Ton	1	213.89	341.82
Total general waste emissions	Ton	/	19.72	142.72
General waste emission intensity	KG / RMB 10,000 of revenue	/	2.17	2.43
Total hazardous waste emissions	Ton	15	61.59	113.64
Hazardous waste emission intensity*2	KG / RMB 10,000 of revenue	20.21	6.77	1.93
Total solid waste emissions	Ton	/	295.20	598.18
Solid waste emission intensity	KG / RMB 10,000 of revenue	/	32.46	10.18

#### Trends in Hazardous Waste Emissions from 2018 to 2020



#### Trends in Solid Waste Emissions from 2019 to 2020



Total solid waste emissions

Solid waste emission intensity

[1] Domestic waste is estimated at 0.5 kg per capita per day.

[2] The Company began commercialisation of 汉利康<sup>®</sup> (rituximab) in China in May 2019. Prior to that, the Company did not commercialise any products and therefore did not generate revenue from sales of products, so the hazardous waste emission intensity was more volatile compared with the data in late stage.

### **Promoting Green Operations**



#### Green Office Concepts of Henlius



Henlius advocates the concept of green office in offices and laboratories, and deeply roots the concept of energy saving and emission reduction in every employee's awareness. By advocating daily behaviors such as turning off lights and regulating air conditioning temperature, the Company is dedicated to improving energy management, reducing energy consumption, and mitigating the negative impact of business operation on environment.

#### **Paperless Office**

During the reporting period, Henlius implemented a paperless office workflow with the Quality Assurance as a pilot department and established three sets of data-based quality management systems to reduce the use of paper by replacing the desk-based office with a more accurate, efficient and environmentally-friendly way of working. 451,889 pages of paper were saved by the three sets of data-based systems of the Quality Assurance in 2020, and further applications are underway. Taking 汉利康<sup>®</sup> (rituximab) as an example, it has saved up to 1,620 pages of paper for a single batch. Looking forward, Henlius will continue to go paperless in the process such as water quality monitoring.

# TURNING CARE INTO SHARD VALUE

Henlius cares for society and actively responds to the government's call for poverty alleviation and disaster relief. The Company works with all sectors of the society and implements corporate social responsibility through various public welfare projects, so as to contribute to building a sustainable ecosystem in the society.



During the reporting period, Henlius donated a total of RMB 7.6 million to charity organisations in 2020, donated materials worth more than RMB 1 million to support the pandemic-stricken areas, and carried out joint research projects to combat the pandemic.

### Creating a Diversified Ecosystem of Diagnosis and Treatment

China is a country with high incidence of breast cancer and gastric cancer. The latest national cancer statistics released in 2019 show that breast cancer has the highest malignant tumor incidence in women with about 304,000 new patients, of which 20%-25% are HER2-positive patients. Gastric cancer ranks the second highest malignant tumor incidence in China, with about 403,000 new patients, of which the HER2-positive rate is 3.7%-20.2%. In 2020, 汉曲优 <sup>©</sup> (Zercepac<sup>®</sup> in the EU), the first Chinese trastuzumab,

was approved in China and the EU, which brings more treatment options for HER2positive breast and gastric cancer patients. As the first Chinese monoclonal antibody biosimilar launched in the EU, 汉曲优<sup>®</sup> is expected to reach more than 80 countries and regions worldwide, opening a new chapter in the internationalisation of Chinese biopharmaceutical R&D achievements. In order to benefit more HER2-positive patients and improve the prevention, diagnosis and treatment of HER2-positive breast and gastric cancers, Henlius officially launched the "Leaving No HER2-positive Patient Behind" project. By joining hands with various partners in different sections, such as drug access, healthcare professional education, testing and diagnosis, big data analysis, patient payment and patient education, the Company is dedicated to improving treatment landscape for HER2-positive patients in China, maximising the benefits for HER2-positive patients while achieving a winwin success for all the parties.

### **Supporting Rural Primary Care**

With the mission of "improving patients' lives by timely providing them with quality and affordable protein therapeutics through technical innovation and operational excellence", Henlius has accelerated the launch of products to benefit the majority of patients since establishment, while actively participating in social welfare and fulfilling social responsibility and obligations. In 2019, Henlius signed a contract with Shanghai Fosun Foundation to formally establish the Shanghai Fosun Foundation Henlius Special Public Welfare Fund, and set up the "Henlius Lanjinglin" volunteer team to expand the volunteer team through continuous recruitment within the Company.

With its own industrial advantages, the Company focuses on and continues to carry out health education and rural medical care projects. Over the years, the Company has held and participated in the "COVID-19 Material Aids", "E.G.G. Walkathon", "Hand in Hand with Children, Caring for the Public" charity auction, "Understanding Lymphoma: A Medical Education Charity Event", Book Donation Activity, Rural Doctor Project, etc., driving a measurable impact on the society and making a difference to the community.





#### The Ecosystem of "Leaving No HER2-positive Patients Behind"

#### **Testing and Diagnostic**

#### 汉曲优 <sup>®</sup> Breast Cancer HER2 FISH Detection Public Welfare Project

The project ran nationwide on 1 December, 2020, covering primary hospitals in tertiary and subtertiary cities, with nearly 1,000 participating hospitals at present. The project aims to improve the HER2 detection rate and positive accuracy rate in primary hospitals, to help breast cancer patients with accurate screening and treatment, and to improve the awareness of breast disease among patients.

#### **Big Data Analysis**

#### The RWS (Real World Study) Project

The project started immediately after the launch of 汉 曲 优  $^{\circ}$  in August 2020, and the first case was enrolled on 1 September. It has attracted the active participation of nearly 10,000 breast cancer physicians and some gastric cancer physicians in hundreds of hospitals, enrolling thousands of patients.

#### **Patient Management**

### 汉曲优 <sup>®</sup> Caring without Distance - Patient Management Project

The project is planned to target thousands of patients and hundreds of physicians from December 2020 to June 2021. Breast cancer patients are given an "online care package" through the cooperation with WeDoctor and thus provided comprehensive disease management in terms of disease awareness, diagnosis, treatment and rehabilitation.

#### Healthcare Professional <u>Educatio</u>n

#### Surgical Demonstration Program

In 2020, dozens of live surgeries were conducted nationwide, and hundreds of physicians at all levels learned through live surgical videos. Good communication channel with famous experts in the industry was established and the operation standard of breast cancer surgery was improved.

#### 汉曲优<sup>®</sup> Wu Jieping Medical Foundation Special Research Fund for Targeted Breast Cancer Treatment

Henlius has established the 汉曲优<sup>®</sup> Wu Jieping Medical Foundation Special Research Fund for Targeted Breast Cancer Treatment and organised an expert committee to review and finally select nearly 100 outstanding projects. This encourages clinicians to translate clinical treatment practice into scientific research data and provide more powerful evidence to support clinical treatment standard.

#### Drug Access

#### **Government Cooperation**

Promoting the study of China's biosimilar medical insurance policy and medical insurance payment standards, and assist in the development of China's bidding policy for biosimilars.

#### **Enterprise Cooperation**

Improving drug accessibility and hospital access coverage.

#### Industry Association Cooperation

In cooperation with PhIRDA, the Company is taking the lead in building a communication platform for the biosimilar industry and introducing industry standards for biosimilars.

#### **Public Welfare Activity**

汉曲优 Rural Medical Service - Public Welfare Activity (Please refer to "Star Projects" for details)



Eight Charity Projects of ONE FOSUN Charity Week " 汉曲优 Rural Medical Service - Public Welfare Activity"



The 16th China Global Awards for Excellence in Public Relations Social Responsibility Bronze Award "Understanding Lymphoma: A Medical Education Charity Event"

#### **Star Projects**

#### Understanding Lymphoma: A Medical Education Charity Event

In order to benefit more lymphatic hematology tumor patients and improve the prevention, diagnosis and treatment of lymphoma disease in China, in January 2019, Henlius and Jiangsu Fosun officially launched the "Understanding Lymphoma: A Medical Education Charity Event" with Shanghai Fosun Foundation's Rural Doctor Project Platform. The project held academic lectures in provincial capitals and the counties of local provinces to provide public welfare training on the prevention, diagnosis and treatment methods of lymphoma disease.

In December 2019, "Understanding Lymphoma: A Medical Education Charity Event" came to a successful end. About 40 experts were organized to deliver training, visit hospitals and consult difficult cases in 11 provinces including Xinjiang, Sichuan, Chongqing, Hainan, Jiangxi, Anhui, Yunnan, Henan, Hunan, Hubei and Guangxi. Over 500 patients and 2000 rural doctors benefited from the project.

#### 汉曲优 Rural Medical Service - Public Welfare Activity

In order to improve diagnosis, treatment and hospital management capabilities in remote villages in China, as well as to give rural female a more scientific understanding of breast cancer, Henlius, together with the Fosun Foundation's Rural Doctor Project Platform, the People's Daily Health application and the Health Times of the People's Daily, jointly launched "汉曲优 Rural Medical Service - Public Welfare Activity". Local well-known breast cancer experts and hospital management teams were invited to visit remote mountain villages, where the project teams provided training to local village doctors and villagers on the prevention, diagnosis and treatment of breast cancer.

Following "Understanding Lymphoma: A Medical Education Charity Event", "汉曲 优 Rural Medical Service - Public Welfare Activity" has become another star charity project of Henlius. The Company is committed to improving rural medical care in China by giving full play to its corporate strengths and realising that villagers can be treated "without leaving the village for minor illnesses and without leaving the county for major ones". In 2020, the project visited more than 10 counties and towns to provide villagers with knowledge of tumor prevention and treatment, paving the way for standardised treatment of diseases in mountain villages. Looking forward, Henlius will join hands with more expert teams to visit different regions, continue to put corporate social responsibility into practice, and strive to make a real difference.

#### Charity Awards

	ONE FOSUN Charity Week Special CSR Activity		
December 2019	"Understanding Lymphoma: A Medical Education Charity Event"		
December 2019	Wisdom Growing Forum "The Best Charity Event in Biopharmaceutical Industry"	Sina Medical	
January 2020	2019 Innovative CSR Activity Award	The 8th China Charity Festival	
November 2020	The 16th China Global Awards for Excellence in Public Relations Social Responsibility Bronze Award	China International Public Relations Association	
	"Understanding Lymphoma: A Medical Education Charity Event"		
November 2020	The 5th "Social Value Co-creation" Excellence Award	CCM CSR Promotion Center	
December 2020	Eight Charity Projects of ONE FOSUN Charity Week	Chanakai Fasur Fasurakai an	
	" 汉曲优 Rural Medical Service - Public Welfare Activity "	Shanghai Fosun Foundation	







On 9 October, 2020, a team of oncologists led by Prof. Qian Liting, President and Party Secretary of Anhui Provincial Cancer Hospital, and Prof. Pan Yueyin, Vice President of Anhui Provincial Cancer Hospital, went to Jinzhai County, Anhui Province, to start the first station of the series of public welfare activities. They conducted charity consultations for local patients and delivered a number of academic lectures for local rural doctors.

As experts from a provincial cancer hospital came visit, many tumor patients arrived at the clinic early and waited in queue. Experts and technical cadres from the Department of Medical Oncology, Department of Gynecologic Oncology, Department of Pediatrics, Department of Head and Neck Oncology Surgery and Breast Treatment Center of Anhui Provincial Cancer Hospital quickly started clinical work after the lecture, and had detailed communications with the tumor patients and their families who came from various towns in Jinzhai County. The visit of top experts is a rare opportunity. For more than 60 doctors and rural doctors from Jinzhai County People's Hospital, Prof. Qian Liting gave a thorough sharing on the new technology and clinical significance of tumor radiotherapy, shed lights on precise radiotherapy, and specifically analyzed the characteristics and clinical benefits of radiotherapy technology. Professor Pan Yueyin, on the other hand, gave a general introduction as well as practical case sharing on some common problems of tumor treatment and problems often encountered by clinicians, and shared the hot topics and cutting-edge advancements in medical oncology.

Given the fact that the health office in Tonggang Village, Jinzhai County, only had broken computers, the team purchased three office computers and donated them to the health office. Prof. Liting Qian and Mr. Yu Cheng, Vice President of Marketing and Commercial Operation of Henlius, donated the computers on behalf of the project team.
Contributing to a Healthy China, Improving Cancer Treatment 汉曲优 Rural Medical Service - Public Welfare Activity Qiongzhong, Hainan



On 22 November, 2020, the second station of 汉 曲 优 Rural Medical Service - Public Welfare Activity was successfully launched. Professor Wang Shusen from Sun Yat-sen University Cancer Center, Professor Liu Jian from Fujian Cancer Hospital, Professor Cao Yali, Vice President of The Third Hospital of Nanchang, Professor Tang Peng from Hainan Cancer Hospital, Professor Zhong Xiaojie from Hainan General Hospital and other nationally-renowned oncologists were invited to Li and Miao Autonomous County, Qiongzhong, Hainan. The team carried out a series of public welfare activities such as gynecology and breast surgery consultation and medical training to make a difference to Qiongzhong people.

In early morning, the team arrived at Qiongzhong County People's Hospital and had a brief discussion with the leaders of Qiongzhong County Government and the hospital. The experts provided opinions on the shortage of talents and encouraged the hospital to actively work with other hospitals to establish oncology departments to improve on-line diagnosis and treatment capability, as well as to deliver more professional skill training for doctors.

After the discussion, the expert team, consisting of several professors, including Wang Shusen, Liu Jian, Tang Peng and Zhong Xiaojie, went to the patient waiting area and began charity consultation. Many patients came from far to line up for charity consultation in early morning. Despite the large number of patients and their families, the experts worked in an orderly, patient and meticulous manner.

After that, Prof. Liu Man and Prof.Yu Yang delivered training for local rural doctor. The topics were "New Advancements in Breast Cancer Surgery" and "Minimally Invasive Surgery for Benign Breast Masses" respectively. The two professors shared many cases.

# **Appendix 1 Key Quantitative Performance**

## Environmental performance\*1

Indicator	Unit	2018	2019	2020
Resource utilization				
Purchased electricity	kWh	9,061,100	10,438,200	20,089,862
Purchased electricity consumption intensity	kWh / RMB 10,000 of revenue	12.21	1,147.95	341.90
Natural gas *2	Cubic metre	1,583,072	1,057,926	2,559,789.50
Natural gas consumption intensity	Cubic metre/ RMB 10,000 of revenue	2,133.23	116.35	43.56
Owned vehicle gasoline usage	Litre	/	13,945.06	0
Total water consumption	Cubic metre	88,141	108,013	233,594
Water consumption intensity	Cubic metre/ RMB 10,000 of revenue	118.77	11.88	3.98
Total consumption of recycled water	Cubic metre	80	100	2,164,709.43
Total packaging materials	Ton	/	7.79	43.02
Packaging material consumption intensity	KG / RMB 10,000 of revenue	/	0.86	0.73
Total investment in environmental protection	RMB 10,000	53	55	255.10
Pollutants				
Nitrogen oxides	Ton	1.01	0.61	0.30
Sulfur dioxide	Ton	0.05	0.05	0.03
Total non-methane hydrocarbons	Ton	0.02	0.02	0.03
Particulate matters	Ton	0	0.03	0*3
Total wastewater discharge	Ton	1,134	2,229	11,285.70
Chemical oxygen demand (COD)	Ton	0.12	0.22	0.64
Ammonia nitrogen(NH <sub>3</sub> -N)	Ton	0.01	0.01	0.01
Total hazardous waste emissions	Ton	15	61.59	113.64
Hazardous wastes by disposal method: incineration	Ton	13.30	56.38	113.64
Hazardous wastes by disposal method: materialization	Ton	1.70	5.21	0*4

Indicator	Unit	2018	2019	2020
Hazardous waste emission intensity	KG / RMB 10,000 of revenue	20.21	6.77	1.93
Total domestic waste *5	Ton	/	213.89	341.82
Total general waste emissions	Ton	/	19.72	142.72
General waste emission intensity	KG / RMB 10,000 of revenue	/	2.17	2.43
Total solid waste emissions	Ton	/	295.2	598.18
Solid waste emission intensity	KG / RMB 10,000 of revenue	/	32.46	10.18
Total greenhouse gas emissions	Ton of CO <sub>2</sub>	9,595.62	9,434	19,667.96
Scope 1 greenhouse gas emissions	Ton of CO <sub>2</sub>	3,427.13	2,328.02	5,534.75
Scope 2 greenhouse gas emissions	Ton of CO <sub>2</sub>	6,168.49	7,105.98	14,133.22
Total greenhouse gas emission intensity	Ton of CO <sub>2</sub> / RMB 10,000 of revenue	12.93	1.04	0.33

[1] As the R&D centres in California do not engage in production activities and the utilization and environmental resource and pollutant emissions are relatively small, they are not covered by the environmental performance in this report.

[2] Henlius mainly consumed the direct energy of diesel in 2018. In order to form inter-annual data comparability, the data of natural gas consumption in 2018 were converted from the diesel consumption.

[3] The data of particulate matters emission are calculated on the basis of the quarterly monitored emission concentrations. Henlius continuously monitors emission concentration of particulate matters, and its emission concentration is far less than the standard limit. The quarterly monitoring results of emission concentration of particulate matters fluctuate to a certain extent, therefore, the total emissions based on the quarterly monitoring results vary on an annual basis. Particulate matters emission in 2020 are below the detection value and cannot be measured.

[4] The disposal company adopts incineration method, so the data for 2020 is 0.

[5] The daily per-capita domestic waste is estimated to be 0.5kg.

## Employment

Indicator	Unit	2018	2019	2020
Employment				
Workforce	Person	735	1,172	1,873
Number of male employees	Person	323	501	876
Number of female employees	Person	412	671	997
Number of employees aged above 50	Person	32	37	32
Number of employees aged between 30 and 50	Person	317	532	807
Number of employees aged between 18 and 30	Person	386	603	1,034
Number of employees working in Chinese mainland	Person	668	1,087	1,833
Number of employees working in Hong Kong, Macao and Taiwan China	Person	40	44	5
Number of employees working in the United States	Person	27	41	35
Number of employees with a doctoral degree	Person	79	103	99
Number of employees with a master's degree	Person	250	427	537
Number of employees with a bachelor's degree	Person	94	484	938
Number of employees with a degree below bachelor	Person	312	158	299
Employee turnover rate	%	14.53	10.12	13.19
Male employee turnover rate	%	/	/	13.35
Female employee turnover rate	%	/	/	13.05
Employee health and safety				
Number of work-related injury	Day	0	0	5
Number of employees who died due to work-related reason	Person	0	0	0
Million hours lost worktime rate	/	0	0	1.75
Employee training				
Expenditures for employee training	RMB 10,000	119	239	63.70
Coverage rate of employee training	%	89.52	93.77	81.69
Coverage rate of male employee training	%	90.09	91.62	80.37
Coverage rate of female employee training	%	89.08	95.38	82.85
Per-capita training hours of employees *1	Hour	14.06	12.99	17.61
Per-capita training hours of male employees *2	Hour	14.14	13.04	16.88
Per-capita training hours of female employees *3	Hour	13.99	12.96	18.25

[1] In 2020, Henlius introduced online E-Learning training. With integrated online and offline training, the per-capita training hours of employees is 17.61 hours. The calculation method is total hours of training for all employees / total number of employees.

[2] The calculation method is total hours of training for male employees/ total number of male employees.

[3] The calculation method is total hours of training for female employees/total number of female employees.

## **Product Quality and Safety**

Indicator	Unit	2019	2020
Total number of violations of law and regulation of products and services in terms of safety and labelling	Piece	0	0
Total number of violations of law and regulation in terms of marketing promotion	Piece	0	0
Total number of violations of law and regulation in terms of customer privacy	Piece	0	0
Proportion of sold or shipped products that need to be recalled due to safety or health reasons	%	0	0
Number of complaints against product and service	Piece	5	0
Complaint handling rate of product and service	%	100	/

## **Supply Chain**

.0

## Anti-corruption

Indicator	Unit	2018	2019	2020
Number of lawsuits that have been filed and concluded against Henlius and its employees	Piece	0	0	0

# **Public Welfare**

Indicator	Unit	2018	2019	2020
Donation to charity organisations	DMD	16,975	4,280,192	7,600,000
Pandemic donation RMB /		/	/	1,000,000

# **Appendix 2 HKEX Index**

## Environmental, Social and Governance Reporting Guide – Content Index

ESG Subject Area, General Disclosures and KPIs Sections						
Environmental						
	General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to air and greenhouse gas emissions, discharges into water and land, and generation of hazardous and non-hazardous waste.	Environmental Protection and Green Operations			
	KPI A1.1	The types of emissions and respective emissions data.	Environmental Protection and Green Operations: Abiding by Green Production			
Aspect A1:	KPI A1.2	Direct (Scope 1) and energy indirect (Scope 2) greenhouse gas emissions (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	Environmental Protection and Green Operations: Abiding by Green Production			
Emissions	KPI A1.3	Total hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	Environmental Protection and Green Operations: Abiding by Green Production			
	KPI A1.4	Total non-hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g . per unit of production volume, per facility).	Environmental Protection and Green Operations: Abiding by Green Production			
	KPI A1.5	Description of emission target(s) set and steps taken to achieve them.	Environmental Protection and Green Operations: Abiding by Green Production			
	KPI A1.6	Description of how hazardous and non-hazardous wastes are handled, and a description of reduction target(s) set and steps taken to achieve them.	Environmental Protection and Green Operations: Abiding by Green Production			
	General Disclosure	Policies on the efficient use of resources, including energy, water and other raw materials. Note: Resources may be used in production, in storage, transportation, in buildings, electronic equipment, etc.	Environmental Protection and Green Operations: Abiding by Green Production			
	KPI A2.1	Direct and/or indirect energy consumption by type (e.g . electricity, gas or oil) in total (kWh in '000s) and intensity (e.g . per unit of production volume, per facility).	Environmental Protection and Green Operations: Abiding by Green Production			
A2: Use of Resources	KPI A2.2	Water consumption in total and intensity (e.g . per unit of production volume, per facility).	Environmental Protection and Green Operations: Abiding by Green Production			
	KPI A2.3	Description of energy use efficiency target(s) set and steps taken to achieve them.	Environmental Protection and Green Operations: Abiding by Green Production			
	KPI A2.4	Description of whether there is any issue in sourcing water that is fit for purpose, water efficiency target(s) set and steps taken to achieve them.	Environmental Protection and Green Operations: Abiding by Green Production			
	KPI A2.5	Total packaging material used for finished products (in tonnes) and, if applicable, with reference to per unit produced.	Environmental Protection and Green Operations: Abiding by Green Production			
Aspect A3: The Environment	General Disclosure	Policies on minimising the issuer's significant impacts on the environment and natural resources.	Environmental Protection and Green Operations: Abiding by Green Production			
and Natural Resources	KPI A3.1	Description of the significant impacts of activities on the environment and natural resources and the actions taken to manage them.	Environmental Protection and Green Operations: Abiding by Green Production			

ESG Subject Are	ea, General Disc	closures and KPIS	Sections
Aspect A4:	General Disclosure	Policies on identification and mitigation of significant climate-related issues which have impacted, and those which may impact, the issuer.	Environmental Protection and Green Operations: Abiding by Green Production
Climate Change	KPI A4.1	Description of the significant climate-related issues which have impacted, and those which may impact, the issuer, and the actions taken to manage them.	Environmental Protection and Green Operations: Abiding by Green Production
B. Social			
Employment ar	nd Labor Practio	ces	
Aspect B1:	General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to compensation and dismissal, recruitment and promotion, working hours, rest periods, equal opportunity, diversity, anti- discrimination, and other benefits and welfare.	Nurturing Talent to Seek Common Development: Employment in Compliance w Law
Employment	KPI B1.1	Total workforce by gender, employment type (for example, full- or part-time), age group and geographical region.	Nurturing Talent to Seek Common Development: Employment in Compliance w Law
	KPI B1.2	Employee turnover rate by gender, age group and geographical region.	Nurturing Talent to Seek Common Development: Employment in Compliance w Law
	General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to providing a safe working environment and protecting employees from occupational hazards.	Nurturing Talent to Seek Common Development: Caring for Employees
Aspect B2: Health and Safety	KPI B2.1	Number and rate of work-related fatalities occurred in each of the past three years including the reporting year.	Nurturing Talent to Seek Common Development: Caring for Employees
	KPI B2.2	Lost days due to work injury.	Nurturing Talent to Seek Common Development: Caring for Employees
	KPI B2.3	Description of occupational health and safety measures adopted, and how they are implemented and monitored.	Nurturing Talent to Seek Common Development: Caring for Employees
Aspect B3:	General Disclosure	Policies on improving employees' knowledge and skills for discharging duties at work. Description of training activities. Note: Training refers to vocational training. It may include internal and external courses paid by the employer.	Nurturing Talent to Seek Common Development
Development and Training	KPI B3.1	The percentage of employees trained by gender and employee category (e.g. senior management, middle management).	Nurturing Talent to Seek Common Development: Caring for Employees
	KPI B3.2	The average training hours completed per employee by gender and employee category.	Nurturing Talent to Seek Common Development: Caring for Employees
	General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to preventing child and forced labour.	Nurturing Talent to Seek Common Development: Employment in Compliance w Law
Aspect B4: Labour Standards	KPI B4.1	Description of measures to review employment practices to avoid child and forced labour.	Nurturing Talent to Seek Common Development: Employment in Compliance w Law
	KPI B4.2	Description of steps taken to eliminate such practices when discovered.	Nurturing Talent to Seek Common Development: Employment in Compliance w

ESG Subject Are	a, General Disc	closures and KPIs	Sections
	General Disclosure	Policies on managing environmental and social risks of the supply chain.	Fostering Win-win Collaboration with Honesty and Reliability
	KPI B5.1	Number of suppliers by geographical region.	Fostering Win-win Collaboration with Honesty and Reliability: Forging Responsible Supply Chains
Aspect B5: Supply Chain Management	KPI B5.2	Description of practices relating to engaging suppliers, number of suppliers where the practices are being implemented, and how they are implemented and monitored.	Fostering Win-win Collaboration with Honesty and Reliability: Forging Responsible Supply Chains
	KPI B5.3	Description of practices used to identify environmental and social risks along the supply chain, and how they are implemented and monitored.	Fostering Win-win Collaboration with Honesty and Reliability: Forging Responsible Supply Chains
	KPI B5.4	Description of practices used to promote environmentally preferable products and services when selecting suppliers, and how they are implemented and monitored.	Fostering Win-win Collaboration with Honesty and Reliability: Forging Responsible Supply Chains
	General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to health and safety, advertising, labelling and privacy matters relating to products and services provided and methods of redress.	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use
Aspect B6:	KPI B6.1	Percentage of total products sold or shipped subject to recalls for safety and health reasons.	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use
Product Responsibility	B6.2	Number of products and service-related complaints received and how they are dealt with.	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use
	KPI B6.3	Description of practices relating to observing and protecting intellectual property rights.	Foundation of Responsibilities Fulfilment: Excellence in Development: Intellectual Property Right Protection
	KPI B6.4	Description of quality assurance process and recall procedures.	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use
	KPI B6.5	Description of consumer data protection and privacy policies, and how they are implemented and monitored.	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use
	General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to bribery, extortion, fraud and money laundering.	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
Aspect B7: Anti-corruption	KPI B7.1	Number of concluded legal cases regarding corrupt practices brought against the issuer or its employees during the reporting period and the outcomes of the cases.	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
	KPI B7.2	Description of preventive measures and whistle-blowing procedures, and how they are implemented and monitored.	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
	KPI B7.3	Description of anti-corruption training provided to directors and staff.	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
Community			
Aspect B8:	General Disclosure	Policies on community engagement to understand the needs of the communities where the issuer operates and to ensure its activities take into consideration the communities' interests.	Turning Care into Shared Value
Community Investment	KPI B8.1	Focus areas of contribution (e.g . education, environmental concerns, labour needs, health, culture, sport).	Turning Care into Shared Value
	KPI B8.2	Resources contributed (e.g . money or time) to the focus area.	Turning Care into Shared Value

# **Appendix 3 GRI Content Index**

Disclosure items	Topics	Sections
GRI 101: Fo	oundation 2016	
GRI 102: G	eneral Disclosures 2016	
Organizat	tional profile	
102-1	Name of the organization	About Henlius
102-2	Activities, brands, products, and services	Company Overview
102-3	Location of headquarters	About Henlius
102-4	Location of operations	Company Overview
102-5	Ownership and legal form	About Henlius
102-6	Markets served	Company Overview
102-7	Scale of the organization	Company Overview
102-8	Information on employees and other workers	Nurturing Talent to Seek Common Development: Employment in Compliance with Law
102-9	Supply chain	Fostering Win-win Collaboration with Honesty and Reliability: Forging Responsible Supply Chains
102-10	Significant changes to the organization and its supply chain	Fostering Win-win Collaboration with Honesty and Reliability: Forging Responsible Supply Chains
102-13	Membership of associations	Fostering Win-win Collaboration with Honesty and Reliability: Promoting Industry Development
Strategy		
102-14	Statement from senior decision-maker	Management Message
Ethics and	d integrity	
102-16	Values, principles, standards, and norms of behavior	Sustainable Development Management: CSR Vision
Governan	nce	
102-18	Governance structure	Foundation of Responsibilities Fulfilment: Excellence in Development: Corporate Governance
Stakeholo	der engagement	
102-40	List of stakeholder groups	Sustainable Development Management: Communications with Stakeholders
102-41	Collective bargaining agreements	Nurturing Talent to Seek Common Development: Caring for Employees
102-42	Identifying and selecting stakeholders	Sustainable Development Management: Communications with Stakeholders
102-43	Approach to stakeholder engagement	Sustainable Development Management: Communications with Stakeholders
102-44	Key topics and concerns raised	Sustainable Development Management: Analysis of Materiality Issues
Reporting	g practice	
102-45	Entities included in the consolidated financial statements	About This Report Company Overview
102-46	Defining report content and topic Boundaries	About This Report
102-47	List of material topics	Sustainable Development Management: Analysis of Materiality Issues
102-48	Restatements of information	About This Report
102-49	Changes in reporting	Sustainable Development Management: Analysis of Materiality Issues
102-50	Reporting period	About This Report
100 51	Date of most recent report	About This Report
102-51	Date of most recent report	About misheport

Disclosure items	Topics	Sections
102-53	Contact point for questions regarding the report	About This Report
102-55	GRI content index	Appendix 2: GRI Content Index
GRI 201: Ec	conomic Performance 2016	
201-1	Direct economic value generated and distributed	About Henlius
201-3	Defined benefit plan obligations and other retirement plans	Nurturing Talent to Seek Common Development: Caring for Employees
GRI 205: A	nti-corruption 2016	
205-1	Operations assessed for risks related to corruption	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
205-2	Communication and training about anti-corruption policies and procedures	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
205-3	Confirmed incidents of corruption and actions taken	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
GRI 206: A	nti-competitive Behavior 2016	
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised Management
GRI 301: M	aterials 2016	
301-1	Materials used by weight or volume	Environmental Protection and Green Operations: Abiding by Green Production
GRI 302: Er	nergy 2016	
302-1	Energy consumption within the organization	Environmental Protection and Green Operations: Abiding by Green Production
302-3	Energy intensity	Environmental Protection and Green Operations: Abiding by Green Production
302-4	Reduction of energy consumption	Environmental Protection and Green Operations: Promoting Green Operations
302-5	Reductions in energy requirements of products and services	Environmental Protection and Green Operations: Promoting Green Operations
GRI 303: W	ater 2016	
303-1	Water withdrawal by source	Environmental Protection and Green Operations: Abiding by Green Production
303-3	Water recycled and reused	Environmental Protection and Green Operations: Abiding by Green Production
GRI 305: Er	nissions 2016	
305-1	Direct (Scope 1) GHG emissions	Environmental Protection and Green Operations: Abiding by Green Production
305-2	Energy indirect (Scope 2) GHG emissions	Environmental Protection and Green Operations: Abiding by Green Production
305-4	GHG emissions intensity	Environmental Protection and Green Operations: Abiding by Green Production
GRI 306: Ef	fluents and Waste 2016	
306-1	Water discharge by quality and destination	Environmental Protection and Green Operations: Abiding by Green Production
306-2	Waste by type and disposal method	Environmental Protection and Green Operations: Abiding by Green Production
GRI 307: Er	nvironmental Compliance 2016	
307-1	Non-compliance with environmental laws and regulations	Environmental Protection and Green Operations: Abiding by Green Production
GRI 308: Su	upplier Environmental Assessment 2016	
308-1	New suppliers that were screened using environmental criteria	Fostering Win-win Collaboration with Honesty and Reliability: Forging Responsible Supply Chains
GRI 401: Er	nployment 2016	
401-1	New employee hires and employee turnover	Nurturing Talent to Seek Common Development: Caring for Employees: Employment in Compliance with Law
401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees	Nurturing Talent to Seek Common Development: Caring for Employees
401-3	Parental leave	Nurturing Talent to Seek Common Development: Caring for Employees
GRI 403: 0	ccupational Health and Safety 2016	

Disclosure items	Topics	Sections				
403-2	Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	Nurturing Talent to Seek Common Development: Caring for Employees				
GRI 404: Training and Education 2016						
404-1	Average hours of training per year per employee	Nurturing Talent to Seek Common Development: Employee Training and Development				
404-2	Programs for upgrading employee skills and transition assistance programs	Nurturing Talent to Seek Common Development: Employee Training and Development				
404-3	Percentage of employees receiving regular performance and career development reviews	Nurturing Talent to Seek Common Development: Employee Training and Development				
GRI 405: Diversity and Equal Opportunity 2016						
405-1	Diversity of governance bodies and employees	Nurturing Talent to Seek Common Development: Employee Training and Development				
GRI 406: Non-discrimination 2016						
406-1	Incidents of discrimination and corrective actions taken	Foundation of Responsibilities Fulfilment: Excellence in Development: Corporate Governance Nurturing Talent to Seek Common Development: Employment in Compliance with Law				
GRI 416: Customer Health and Safety 2016						
416-1	Assessment of the health and safety impacts of product and service categories	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use				
416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use				
GRI 417: Marketing and Labeling 2016						
417-1	Requirements for product and service information and labeling	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised management				
417-2	Incidents of non-compliance concerning product and service information and labeling	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised management				
417-3	Incidents of non-compliance concerning marketing communications	Foundation of Responsibilities Fulfilment: Excellence in Development: Compliance Operations and Optimised management				
GRI 418: Customer Privacy 2016						
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	Innovating while Maintaining Quality: Ensuring the Safety of Drug Use				

# **Appendix 4 Feedback**

In order to continuously improve the sustainable development of Henlius, we would like to collect your useful feedback. We sincerely thank you for your valuable suggestions on this report.

Your Information:							
Name:		Unit:	Unit:				
Contact Number:		Email Addre	Email Address:				
Your Feedback:							
1. In general, the 2020 Henlius CSR Report is:							
Very good	Quite good	Okay	Not so good	Not good at all			
2. The disclosure of the 2020 Henlius CSR Report is:							
Very informative	Quite informative	Okay	Not so informative	ONot informative at all			
3. The quality of information disclosed in the 2020 Henlius CSR Report is:							
Very high	Quite high	Okay	Quite low	Very low			
4. Which of the following areas in the 2021 Henlius CSR Report need to be strengthened:							
ldea elaboration	Data & charts	Case studies					
5. In the 2021 Henlius CSR Report, you would like to add a section on:							
Corporate governance, in particular:							
Environmental protection, in particular:							
Social advancement, in particular:							
Others, in particular:							

**Contact Us:** 

Address: 9/F, Innov Tower, Zone A, No. 1801 Hongmei Road, Xuhui District, Shanghai Postcode: 200233 Website: www.henlius.com Tel: +86 21 33395800 Email: PR@henlius.com



# **ASSURANCE STATEMENT**

# SGS-CSTC'S REPORT ON SUSTAINABILITY ACTIVITIES IN THE SHANGHAI HENLIUS BIOTECH, INC. FOR 2020

## NATURE AND SCOPE OF THE ASSURANCE/VERIFICATION

SGS-CSTC STANDARDS TECHNICAL SERVICES CO., LTD. (thereafter as "SGS) was commissioned by SHANGHAI HENLIUS BIOTECH, INC. (thereafter as "HENLIUS") to conduct an independent assurance of the Corporate Social Responsibility Report for 2020 (thereafter as "the Report"). The scope of the assurance, based on the SGS Sustainability Report Assurance methodology, included the text, and data in accompanying tables, contained in the Report. On-site assurance process was executed at 9/F, Innov Tower, Zone A, No. 1801 Hongmei Road, Xuhui District, Shanghai, P. R. China. Data and information of other companies were not included in this assurance process.

The information in the Report and its presentation are the responsibility of the management, governing body of HENLIUS. SGS has not been involved in the preparation for any of the materials included in the Report.

Our responsibility is to express an opinion on the text, data, graphs, and statements within the scope of verification with the intention to inform all HENLIUS's stakeholders.

The SGS protocols are based upon internationally recognized guidance, including the reporting principles contained within the HKEX listing rules appendix 27 *Environmental, Social and Governance Reporting Guide* and the guidance on levels of assurance contained within the AA1000 series of standards and guidance for Assurance Providers.

This report has been assured at a moderate level of scrutiny using our protocols for:

- evaluation of content veracity;
- evaluation of the report against the HKEX Environmental, Social and Governance (ESG) Reporting Guide (2015).

The assurance comprised a combination of pre-assurance research, interviews with relevant employees located at 9/F, Innov Tower, Zone A, No. 1801 Hongmei Road, Xuhui District, Shanghai, P. R. China; documentation and record review and assurance with external bodies and/or stakeholders where necessary.

Financial data drawn directly from independently audited financial accounts has not been checked back to its source as part of this assurance process.

## STATEMENT OF INDEPENDENCE AND COMPETENCE

SGS is the world's leading inspection, verification, testing and certification company. We are recognized as the global benchmark for quality and integrity with a network around the world. SGS affirm our independence from HENLIUS being free from bias and conflicts of interest with the organisation, its subsidiaries and stakeholders.

The assurance team was assembled based on their knowledge, experience, and qualifications for this assignment, and comprised auditors registered with CSR Lead Assuror, CCAA Registered ISO 14001 Auditor and ISO 45001 Auditor.

## VERIFICATION/ ASSURANCE OPINION

On the basis of the methodology described and the verification work performed, we are satisfied that the information and data contained within the Report verified is accurate, reliable and provides a fair and balanced representation of HENLIUS sustainability activities in 2020.

SGS believe that HENLIUS has chosen an appropriate reporting guide, and information contained within the Report can be used by the Reporting Organisation's Stakeholders.

## CONCLUSIONS, FINDINGS AND RECOMMENDATIONS

In our opinion, the Report is presented in accordance with the reporting rules and the KPIs disclosures of the HKEX listing rules appendix 27 *Environmental, Social and Governance Reporting Guide*.

#### **Reporting Rules**

### Materiality

HENLIUS conducts a stakeholder survey and internal planning to report the ESG issues by stakeholders' concerns with materiality. SGS recommended that HENLIUS should plan more methods and channels to determine the materiality topics, which would enhance the materiality and adequacy.

### Quantitative

HENLIUS performs the statistics and analysis for some KPIs, plans the management methods and some KPIs, refers to the criterions and international general regulations, and reports the disclosures' impact and purpose. Some comparative yearly data could better help stakeholders to evaluate its management system's effectiveness and make decisions.

### Balance

HENLIUS shows the balance reporting rule in the Report and reports environmental, social and governance issues accurately.

### Consistency

HENLIUS plans the disclosure methodologies with consistency for report content and data statistics at all levels in the company, in addition, remarks and interpretations were marked in the Report to help stakeholders make a clear comparison.

## Limitations of assurance

The assurance scope only covered the Headquarters of HENLIUS and did not involve assurance of the original data of other sites. The data for assurance of report information was from the Headquarters.

The assurance process only involved interviews with the heads of relevant departments and certain employees and consultation with relevant documents didn't involve external stakeholders.

As the financial information in the 2020 financial report has passed independent assurance, the assurance does not contain traceability and assurance of such information.

Signed:

Koh5

For and on behalf of SGS-CSTC David XIN Director Knowledge 16/F Century Yuhui Mansion, No. 73, Fucheng Road, Beijing, China May. 27, 2021





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