



Affordable Innovation · Reliable Quality

Patient-centric treatment for global health

Henlius Company Introduction
2025

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Henlius Overview



About Henlius

Henlius is a rapidly growing biopharmaceutical provider that develops, manufactures, and distributes leading biologics and mAb oncology treatments in about **60 countries around the world**, serving over **900,000 patients**. Our mission is to improve patients' lives by timely providing them with quality and affordable protein therapeutics through technical innovation and operational excellence.



Biopharmaceuticals at Global Scale



9
Products Approved Globally



~ 60
Approved Countries



1,150+
GMP Commercial Batches



900,000
Patients Benefited

Milestones

2010

Henlius founded in Shanghai



2016

First facility in operation



2019

Listed on HKEX (2696.HK)



2020

First facility obtains EU GMP certification



2022

Second facility commences commercial production



2023

On a total revenue of \$759 MM, the company achieved a net profit of \$76.9 MM



2024

Second facility obtains U.S. GMP certification



2025

Included in MSCI Global Small Cap Indexes



2010–2019

Foundation & Platform Validation

2020–2024

Global Expansion & Innovation Acceleration

2025–Today

Global Breakthrough & Pipeline Synergy



2019

HLX01 (rituximab) launched and becomes the first biosimilar approved in China

2020

HLX02 (trastuzumab) launched in the EU & China

HLX03 (adalimumab) launched in China

2021

HLX04 (bevacizumab) launched in China

2022

Serplulimab, the world's 1st anti-PD-1 mAb in 1L SCLC, launched in China

2024

HLX02 (trastuzumab) launched in the U.S.

Neratinib launched in China

2025

Serplulimab launched in the EU

BILDYOS® (denosumab) & BILPREVDA® (denosumab) launched in the U.S. and the EU

Fovinaciclib launched in China

Now

Multiple biologics and novel assets in global clinical trials

Addressing Therapeutic Areas of Highest Demand

Primary focus:

Henlius develops biological **oncology treatments** for cancers with the highest prevalence rates and highest clinical needs.



Breast Cancer



Lung Cancer



Gastric Cancer



Colorectal cancer



Other solid tumors
and hematology

Secondary focus:

Henlius also develops biomedicine for non-oncology disorders including:



Autoimmune



Metabolic



Ophthalmology

In-House, Top Industry Talent

Leadership team with experience at Amgen, Bayer, GSK, Roche and other leading pharmaceutical companies.

Top industry talent with expertise in pharmaceutical R&D, clinical development, manufacturing, commercialization, regulatory affairs, CMC, and quality and compliance.

Complete in-house functions for entire development chain, from discovery to research to approvals.





3,515

employees



953

R&D staff



35%

female executives



808

postgraduates

Veteran Executives



Dr. Jason Zhu
Executive Director
Chief Executive Officer

- ✓ More than 20 years in clinical research industry.
- ✓ Had cooperated with over 70 China local pharmaceutical and biotech companies and led the design and execution of over 100 phase I to IV clinical trials.
- ✓ Previously served as Founder and CEO of PPC China, Global Vice President of IQVIA, China GM of Omnicare.
- ✓ Had previously worked as a physician in Huashan Hospital.



Wei Huang
President



Kurt Yu
Chief Commercial Officer
SVP



Ping Cao
Chief Business Development Officer
SVP



Simon Hsu
Chief Technology Officer
SVP



James Guo
SVP



Jessie Li
Chief Human Resource Officer
SVP



Jijun Yuan
Chief Scientific Officer



Frank Ye
Chief Quality Officer
VP



Max Mao
Chief Financial Officer
VP



Ming Yang
VP of Immune-Oncology
Business Unit



Wallis Zeng
Vice President



Jing Li
VP of Global Product
Development



Jin Li
VP of Regulatory Affairs



Miaojie Chen
VP of Legal and Compliance



Arthur Sheng
GM of Global Strategy & PMO



Qingyu Wang
China Chief Medical Officer
GM of Clinical Development Department



Ely Benaim
U.S. Chief Medical Officer



Guangri Sun
Deputy General Manager of Oncology
Business Unit



Nancy Wang
Board Secretary
GM of Public Relations



Our Advantage



Designed for efficient, affordable, effective treatments



Comprehensive internal and whole process R&D for efficient, fast, and low-risk development



1,150 batches of GMP commercial production delivered at global standards



Rising to the top through efficient and global commercialization

Comprehensive R&D

Combining investment, systems, talent, facilities and partnerships for the highest-quality innovation at all stages of research and development



Early Discovery

- Leveraging advantages in antibody technology to expand new modalities of drugs.
- Internal innovation supplemented by external licensing.
- Pipeline contains ~50 molecules in R&D. Henlius Advanced Pre-clinical platforms: Tri-specific TCE Platform, Hanjugator™ ADC Platform, HAI Club

Clinical Development

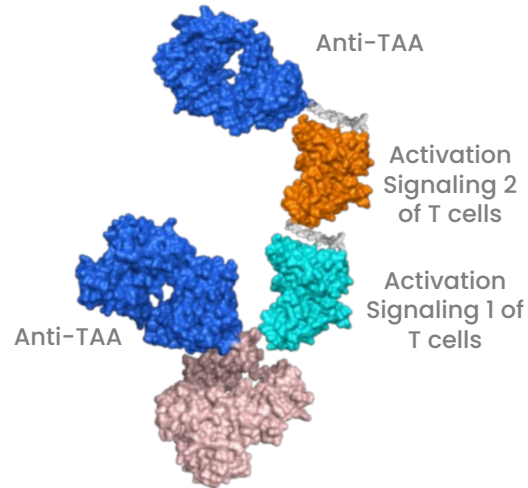
- Full-cycle management system with in-house team, unique in the biopharma industry.
- 19 clinical assets
- 30+ clinical studies

Regulatory Development

- Diversified innovation that combines industry leading in-house R&D with international development partnerships to develop and launch effective, fast, and affordable products.
- Global RA Team with in-depth knowledge of registration paths for different markets
- 6 products launched, 4 ODDs granted by FDA and EC and over 140 clinical approvals worldwide.

Henlius Advanced Platforms

Tri-specific T cell Engager



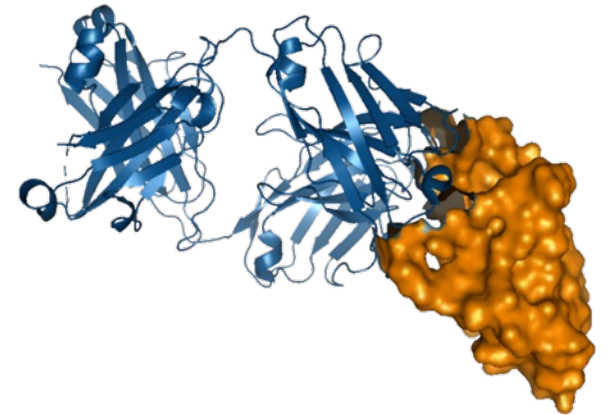
- Longer persistence of Activated T Cell
- Greater Efficacy in solid tumor Treatment
- Enhanced Safety with lower CRS Risks

Hanjugator™ ADC Platform



- Expanded clinical therapeutic window
- Overcome resistance to widely used payloads
- Combination of multiple payload mechanisms

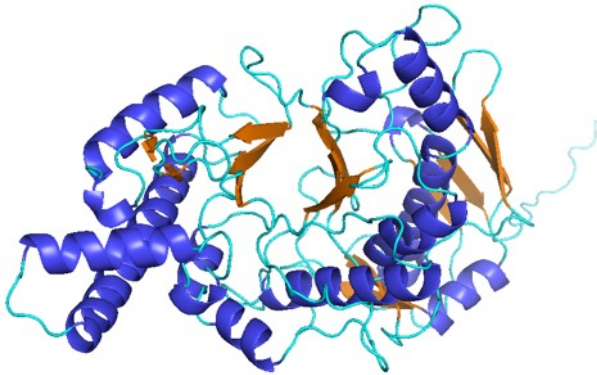
HAI Club Platform



- Identification of Novel drug targets
- Cost-effective Research & Development
- Improved Success rate in drug discovery

Henlius Advanced Platforms

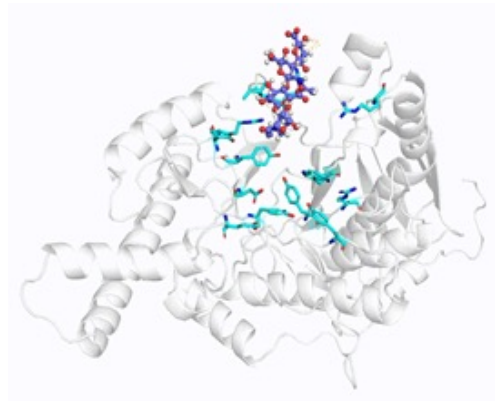
rHuPH20 1.0



- Identical sequence as Halozyme HYLENEX®
- Ideal choice for biosimilars and innovative drugs

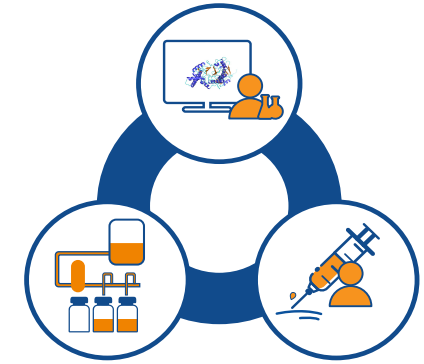
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HENZOZYME



- Henlius proprietary hyaluronidase
- Excellent stability and adaptable for multiple complex scenarios
- Ideal choice for innovative drugs

Formulation Development



- Development platform based on AI+ technology
- High concentration formulation development
- Co-formulation development with different types of hyaluronidase

Advanced Manufacturing & Quality Control

Competitive production capacity that meets the GMP standards from China, EU, and US

3 production facilities in Shanghai – China’s tech, finance, and logistics hub



Xuhui Site

since 2019

- 24,000L commercial production capacity
- GMP-certified from China, the EU, and PIC/S members (Brazil, Indonesia)



Songjiang Site I

since 2022

- 24,000L commercial production capacity
- GMP-certified from China, the EU, and the U.S.
- ISO 14001:2015 and ISO 45001:2018 dual certifications



Songjiang Site II

Groundbreaking in 2019

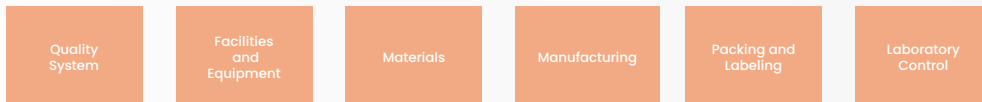
- Phase I and II 36,000L capacity
- One of the largest biomedicine manufacturing facilities in China
- GMP-certified from the EU and the U.S.

Full Product Lifecycle Quality Control

Successfully completed nearly 100 inspections/audits

100% Pass Rate with FDA & EMA

Rigorous quality control systems in place for each stage of manufacturing:



Commercialization

Global



A business commercialization model built for expanding internationally.

~60 countries recognize Henlius products

Efficient



Industry-leading speed in bringing medicines from the approval process to market while being highly competitive on arrival.

1,500+ in-house personnel for entire marketing and domestic sales cycle

Partnerships

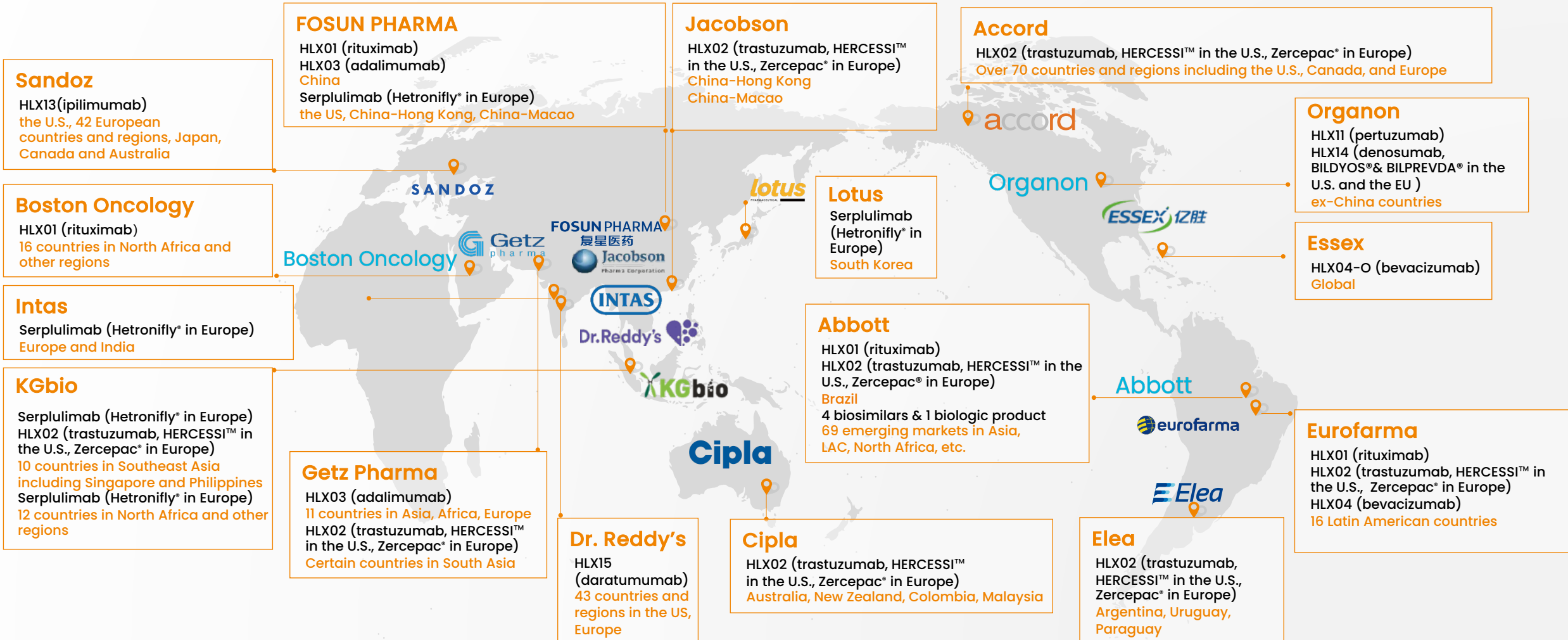


International growth in key regions through commercial and R&D partnerships with leading global pharmaceutical companies.

20+ global pharmaceutical partnerships

Global Commercialization

Henlius leverages its strengths of R&D and manufacturing in China while partnering with global pharmaceutical companies to expand commercialization around the world.











Our Products








Product portfolio and pipeline



 Innovative mAb
  small molecule
  Innovative ADC
  Biosimilar mAb

 Innovative fusion protein
  Innovative multi-specific antibody

 Bridging study in U.S.
  MAA under EMA review
  Approved in Global markets

 BLA under FDA review
  Global MRCT

(1) Exclusive rights in China (excl. Taiwan), several countries in Southeast Asia, and other selected countries and regions; Phase 1b/2a conducting in countries such as China and the U.S. (2) IND approvals obtained in China/the U.S. and granted FDA Fast Track Designation. (3) IND approvals obtained in China/the U.S./Japan/Australia (4) Approved in ~40 countries, including China, the UK, Germany, India, Singapore, trade name: Hetrionify® in Europe. Business partners: KGBio/Fosun Pharma/Intas. (5) Business partner: Shanghai Jingze. (6) Business partner: Dr. Reddy's, etc. (7) Business partner: Sanofi. (8) IND approvals obtained in China/the U.S. (9) IND approvals obtained in China/the U.S./Japan/the EU. (10) Exclusive license obtained in China. (11) Approved in countries such as China and Peru. The first biosimilar approved in China. Business partners: Fosun Pharma/Eurofarma/Abbott/Boston Oncology. (13) NDA under review in China. IND approvals obtained in Australia/the U.S./Singapore/EU countries, etc. Business partner: Essex. (14) The development and exclusive commercialization rights obtained in China and select ex-China markets. (15) Exclusive license obtained in China. Phase 3 MRCT enrolling globally. IND approval obtained in China. (16) Approved in the U.S. and the EU. Marketing applications under review in Canada. Business partner: Organon. (17) Marketing applications under review in China, the U.S. and the EU. Business partner: Organon. (18) The first rituximab approved for the indication in China. (19) Approved in 50+ countries, including China, U.S., the UK, Germany, France and Australia, trade name in U.S.: HERCESSI™, Trade name in Europe: Zercept®. Business partners: Accord/Cipla/Jacobson/ Elea/ Eurofarma/ Abbott/ KGBio/ Getz. (20) Business partners: Fosun Wanbang/ Getz Pharma. (21) Approved in countries such as China and Bolivia. Business partners: Eurofarma. (22) Exclusive license obtained in China. (23) Commercialization in China.

Approved and Impacting the World

Serplulimab

The world's first anti-PD-1 mAb for the first-line treatment of SCLC

Indications:

- ✓ sqNSCLC
- ✓ ES-SCLC
- ✓ ESCC
- ✓ nsNSCLC

- First approved in China in 2022, followed by several Southeast Asian countries and then the EU in 2025, with authorizations now in about 40 countries and regions
- Granted ODDs by the U.S. FDA and the EC in SCLC
- Serplulimab ex-China partners include Fosun Pharma, KGbio, Intas, and Lotus
- Multiple Phase 3 MRCTs and a bridging head-to-head trial in the U.S.
- Over 5,000 subjects enrolled in China, the U.S., Japan, Spain, Germany, and other countries and regions



HLX02 Trastuzumab

Primary markets: China, US, EU

Indications:

- ✓ Early breast cancer
- ✓ Metastatic breast cancer
- ✓ Metastatic gastric cancer

- First approved in the EU, followed by China and then the US in 2024, with authorizations now in over 50 countries and regions
- Clinical results published in *BioDrugs*, *Cancer Chemotherapy and Pharmacology*, and *ESMO*
- Collaboration with global partners such as Abbott, Accord, Eurofarma, KGbio, and ELEA to enter more markets



Approved and Impacting the World

HLX14 Denosumab (BILDYOS®)

- ✓ The U.S.: approved by the FDA in Aug. 2025 for all five indications of the reference product, including osteoporosis
- ✓ The EU: approved by the EC in Sep. 2025
- ✓ Canada: NDS accepted in Sep. 2024



HLX14 Denosumab (BILPREVDA®)

- ✓ The U.S.: approved by the FDA in Aug. 2025 for all three indications of the reference product, including cancer-related bone disease
- ✓ The EU: approved by the EC in Sep. 2025
- ✓ Canada: NDS accepted in Sep. 2024



HLX01 Rituximab

- ✓ First Chinese biosimilar
- ✓ Approved in 2019



HLX03 Adalimumab

- ✓ Henlius first product to treat autoimmune diseases
- ✓ Exclusive license and collaboration agreement in 11 countries



Approved and Impacting the World

HLX04 Bevacizumab

- ✓ High-quality option for lung, colorectal and other cancers
- ✓ Approved in 2021
- ✓ Exclusive license and collaboration agreement in 15 LatAm countries, semi-exclusive in Brazil.



HLX901 Neratinib

- ✓ Reduces the risk of recurrence of early-stage HER2-positive breast cancer
- ✓ Approved in 2024



HLX902 Rituximab

- ✓ For the treatment of advanced HR+/HER2- breast cancer in patients who are initiating or have progressed on endocrine therapy
- ✓ Approved in 2025



Next in Line: Global Potential in Motion

HLX43

Dual mechanism of action

- Synergic efficacy of ADC&immune checkpoint inhibitor(ICI)

DAR~8

- Has a homogeneous and high drug-to-antibody ratio of ~8



Cleavable tripeptide linker

- Stable in plasma & cleaved in TME, achieving dual release of payload both intracellularly (internalization) and extracellularly
- Strong bystander effect ensures payload be enriched in tumor tissues, improving the therapeutic index

DNA topoisomerase 1 inhibitor payload

- Strong bystander effect
- Shorter systemic half-life & higher plasma clearance rate, enabling a better safety profile

Humanized anti-PD-L1 IgG1 mAb

- Proprietary Ab backbone with high affinity and rapid internalization rate

- Biomarker-independent ADC with IO activity, potential BIC
- Outstanding efficacy across multiple tumor types, particularly in heavily treated NSCLC and TSCC (thymic squamous cell carcinoma)
- Efficacy in various types of NSCLC (including squamous and non-squamous, with or without EGFR mutation, with or without brain/liver metastasis, PD-L1 positive and negative)
- Favorable safety profile, low hematologic toxicity
- Monotherapies and combination therapies with serplulimab are ongoing

HLX22



- Granted ODDs by the U.S. FDA and the EC in GC
- Dual-epitope HER2 therapy boosts HER2 internalisation by 40–80%, with the potential to break 1L treatment barriers in HER2+ GC
- Phase 2 shows sustained PFS/OS benefit and 80% reduction in the risk of progression or death with >2-year follow-up
- Phase 3 MRCT: head-to-head comparison vs 1L SOC (trastuzumab + chemotherapy ± pembrolizumab)
- Ongoing trial in HER2-low, HR+ breast cancer; exploratory potential in other cancers

The Future Is Ours Together

Partner with Henlius to build the future of global biopharmaceuticals that is more efficient, effective, and innovative.

Delivering cutting edge treatments

Maximum profitability

Expanding into new markets

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Henlius

THANKS