

Henlius (2696.HK)

Company Introduction

Dr. Jason Zhu, CEO & Executive Director

January 2026



Shanghai Henlius Biotech, Inc.

Forward looking statements

Shanghai Henlius Biotech, Inc. (the "Company", together with its subsidiaries, the "Group") provides the following cautionary statement: This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected or targeted revenues, margins, earnings per share or other financial or other measures, as well as the Group's pipeline products and their expected development, regulatory approval and commercialisation timelines (including the Financial Ambition Statements (as defined below) described in this document). Although the Group believes its expectations and targets are based on reasonable assumptions and has used customary forecasting methodologies used in the biopharmaceutical industry and risk-adjusted projections for individual products (which take into account the probability of success of individual clinical trials, based on industry-wide data for relevant clinical trials at a similar stage of development), any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and the Group undertakes no obligation to update these forward-looking statements. The Group identifies the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Certain statements contained in this document that are not statements of historical fact constitute forward-looking statements, notwithstanding that such statements are not specifically identified. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond the Group's control, include, among other things: the risk of failure or delay in delivery of pipeline or launch of new products, considering that most of the Group's drug candidates are still under development and are in the clinical development stages, and the course of clinical development involves a lengthy and expensive process with uncertainties in various aspects, as there can be no assurance from the Group for the development and clinical results, and that if the clinical development and regulatory approval process of the drug candidates are delayed or terminated, the successful development and commercialisation of the Group's drug candidates in a timely manner may be adversely affected; the risk of failure to meet regulatory or ethical requirements for medicine development or approval; the risk of failures or delays in the quality or execution of the Group's commercial strategies; the risk of pricing, affordability, access and competitive pressures from pharmaceutical companies around the world in respect of various factors such as indication treatment, drug novelty, drug quality and reputation, breadth of drug portfolio, manufacturing and distribution capacity, drug price, breadth and depth of customer coverage, consumer behaviour and supply chain relationships; the risk of unfavourable policies to the Group, which may include the advancement and implementation of the relevant centralised procurement policies in the People's Republic of China; the risk of failure to maintain supply of compliant, quality products; the risk of illegal trade in the Group's products; the impact of reliance on third-party goods and services; the risk of failure in information technology or cybersecurity; the risk of failure of critical processes; the risk of failure to collect and manage data in line with legal and regulatory requirements and strategic objectives; the risk of failure to attract, develop, engage and retain a diverse, talented and capable workforce; the risk of failure to meet regulatory or ethical expectations on environmental impact, including climate change; the risk of the safety and efficacy of marketed products being questioned; the risk of adverse outcome of litigation and/or governmental investigations; intellectual property-related risks to the Group's products; the risk of failure to achieve strategic plans or meet targets or expectations; the risk of failure in financial control or the occurrence of fraud; the risk of unexpected deterioration in the Group's financial position; the risk of any natural disasters or other unanticipated catastrophic events such as earthquakes, fires, terrorist attacks and wars; and the impact that global and/or geopolitical events may have, or continue to have, on these risks, on the Group's ability to continue to mitigate these risks, and on the Group's operations, financial results or financial condition. There can be no guarantees that the Company's pipeline products will receive the necessary regulatory approvals, be successfully developed, manufactured, or commercialised. This presentation includes references to pipeline products that are being investigated in current or future clinical trials, and as such have not been approved by any regulatory agency. For the Group's latest product portfolio and pipeline, see Henlius official website: <http://www.henlius.com>.

The basis of the Company's ambitions, forecasts and targets in this document (the "Financial Ambition Statements") is derived from the Company's most recent risk-adjusted mid- and long-term plans, adjusted for developments in the business since those plans were finalised. Financial Ambition Statements presented are based on management's risk-adjusted projections for individual products and individual clinical trials. Estimates for these probabilities are based on industry-wide data for relevant clinical trials in the biopharmaceutical industry at a similar stage of development adjusted for management's view on the risk profile of the specific asset. Estimates are based on customary forecasting methodologies used in the biopharmaceutical industry. The development of biopharmaceutical products has inherent risks given scientific experimentation and there are a range of possible outcomes in clinical results, safety, efficacy and product labelling. Clinical results may not achieve the desired product profile and competitive environment; pricing and reimbursement may have material impact on commercial revenue forecasts. By their nature, forecasts are based on a multiplicity of assumptions and actual performance in future years may vary, significantly and materially, from these assumptions. The Financial Ambition Statements in this document are based on stated exchange rates. All subsequent written and oral forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements referenced above. The Company undertakes no obligation to update those statements based on future currency movements. This document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction. By attending the presentation relating to this document, or by reading this document, you agree to be bound by the above limitations.

Henlius (2696.HK): A Biopharma Company from China to the World



Benefiting 950,000+ Patients



Henlius' Five Core Global Competencies

R&D Capabilities

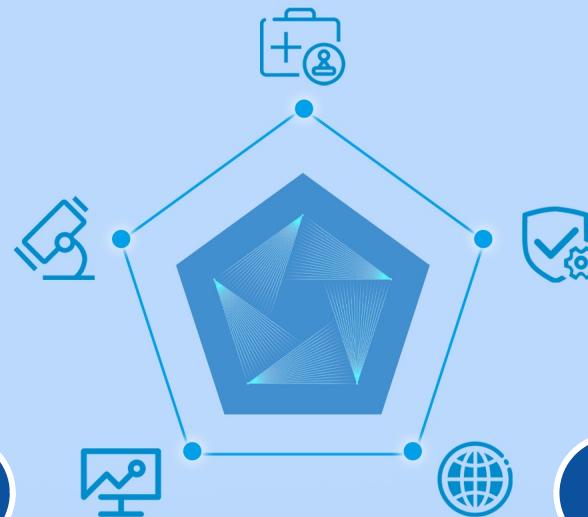
- **50+** early-stage molecules, **~70%** BIC, **~15%** FIC, including ADC, IO, multi-Abs, peptide, small molecule inhibitors, etc.

Regulatory Affairs

- **66** NDAs approved globally, **4** BLAs approved by FDA
- **164** INDs approved globally

Clinical Operations

- In-house global clinical teams, **~520** in China, **~40** in the US, **~20** in RoW
- Covering **1,000+** clinical research centers spread across **20+** countries



Manufacturing & Quality Mgmt

- **>1,150** commercial GMP batches
- GMP-certified by multiple regulatory authorities (incl. FDA, EMA, NMPA)

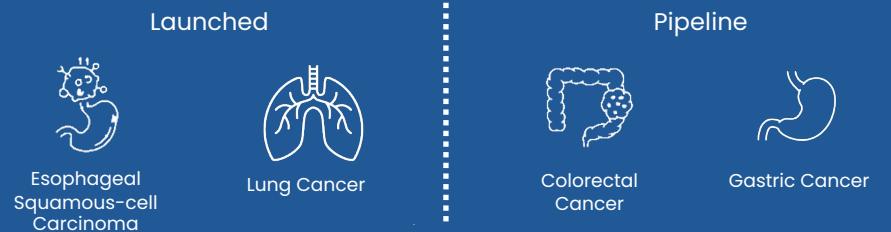
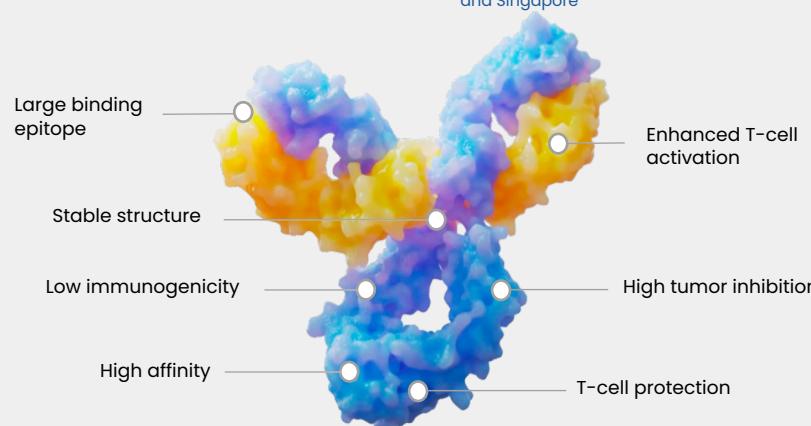
Global Commercialization

- **~1,600** oncology commercialization professionals in China
- **>20** overseas sales partners, products are sold in **~60** countries and regions

Serplulimab (PD-1 mAb) : Potential Best-in-class PD-1 Antibody with Global Market Opportunity

Serplulimab (PD-1) Serplulimab

HANSIZHUANG	Zerpidio®	Hetronify®	Olizu®
Mar. 2022 Launched in CN	Dec. 2023 Launched in SEA	Feb. 2025 Launched in EU May.-Jun. 2025 Launched in UK, India and Singapore	Nov. 2025 Launched in Peru



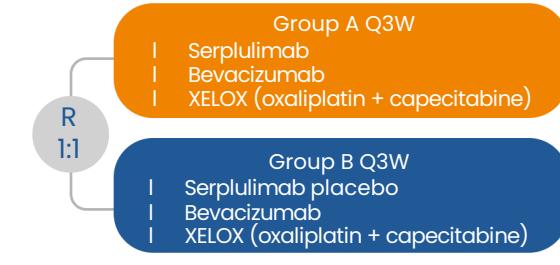
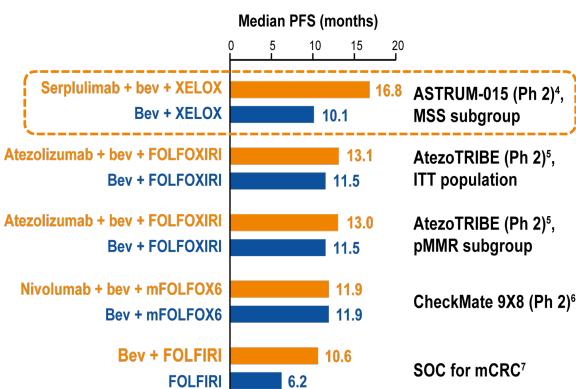
bev, bevacizumab.

1. Horn L, Mansfield AS, Szczesna A, et al. N Engl J Med. 2018; 2. Paz-Ares L, et al. Lancet. 2019 Nov 23; 3. Ying Cheng, et al. 2025 ASCO. Abstract #214. 4. J Clin Oncol 43, 170(2025) Volume 43, Number 4_suppl; 5. J Clin Oncol 41, 2023 (suppl 16; abstr 3500); 6. Lenz, H.-J., et al. J Clin Oncol 40, 4_suppl.008 (2022). 7. Hurwitz, H. et al. N Engl J Med 350, 2335-2342 (2004)

Phase 3 ASTRUM-005 in 1L SCLC, orphan drug designation granted in the US and EU

Regimen	IMpower133 ¹ atezolizumab+ chemo vs chemo	CASPIAN ² durvalumab+ chemo vs chemo	ASTRUM-005 ³ serplulimab+ chemo vs chemo
No. of patients	403 (1:1)	537 (1:1)	585 (2:1)
Liver metastasis, %	8.5	10	12.9
Median follow up, month	59.4	39.4	42.4
Median OS, month	12.3 vs 10.3 (2.0↑) HR = 0.76	12.9 vs 10.5 (2.4↑) HR=0.71	15.8 vs 11.1 (4.7↑) HR=0.60
OS rate, %	4y: 13 vs NE 3y: 16 vs NE	4y: not disclosed 3y: 17.6 vs 5.8	4y: 21.9 vs 7.2 3y: 25.3 vs 10.1

Phase 2/3 results of ASTRUM-015 in 1L MSS mCRC patients

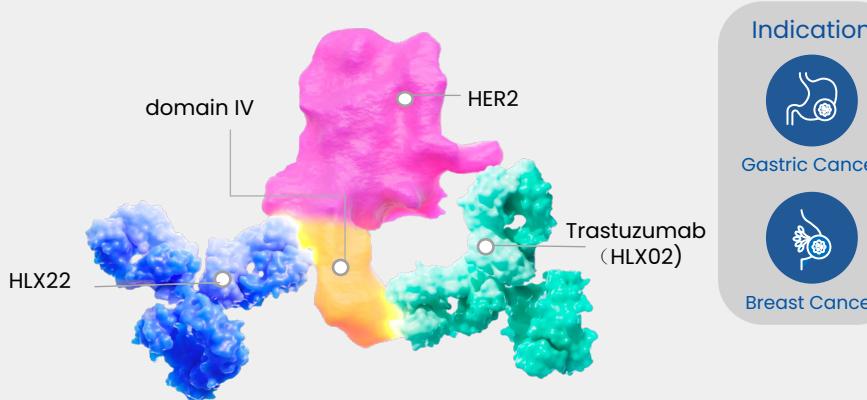


Primary Endpoints: PFS, OS

Phase 3 registrational trial in the perioperative treatment of gastric cancer met primary endpoint and granted Breakthrough Therapy Designation and Priority Review by China NMPA. It is the world's first perioperative regimen for gastric cancer to replace adjuvant chemotherapy with immunotherapy monotherapy.

HLX22 (novel epitope HER2 mAb): a HER2 Monoclonal Antibody Poised to Succeed in the KEYNOTE-811 Era

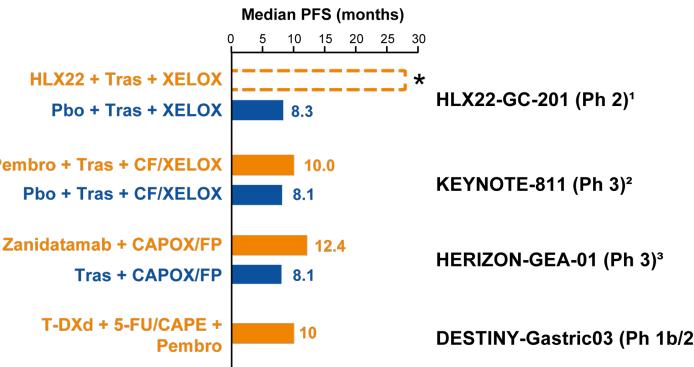
HLX22 (novel epitope HER2)



- Dual-epitope HER2 therapy
- Boosts HER2 internalization by 40–80%
- Potential to break 1L treatment barriers in HER2+ GC

- Phase 2 1L HER2+ GC: sustained PFS/OS benefit
- Phase 3 1L HER2+ GC MRCT: head-to-head comparison vs 1L SOC (trastuzumab + chemotherapy ± pembrolizumab)
- Phase 2 2L HER2-low breast cancer trial ongoing

HLX22 has significantly prolonged PFS and manageable safety profile (median follow-up period of 28.5 months).



	HLX22+ Tras + XELOX (n=31)	Zanidatamab + CAPOX/FP (n=304, 300 patients treated)
TEAE Leading to death	0 (0.0%)	25 (8.2%)
TRAE, Any Grade	30 (96.8%)	296 (97.0%)
TRAE, Grade≥3	9 (29.0%)	180 (59.0%)
Discontinued due to TRAE	2 (6.5%)	105 (34.4%)
Treatment-related Diarrhea, Any Grade	<15%	233 (76.4%)
Treatment-related Diarrhea, Grade≥3	0 (0.0%)	61 (20.0%)

HLX22-GC301 MRCT led by top global clinical researchers

Dr. Shen Lin
Beijing Cancer Hospital
CSCO GC Chair

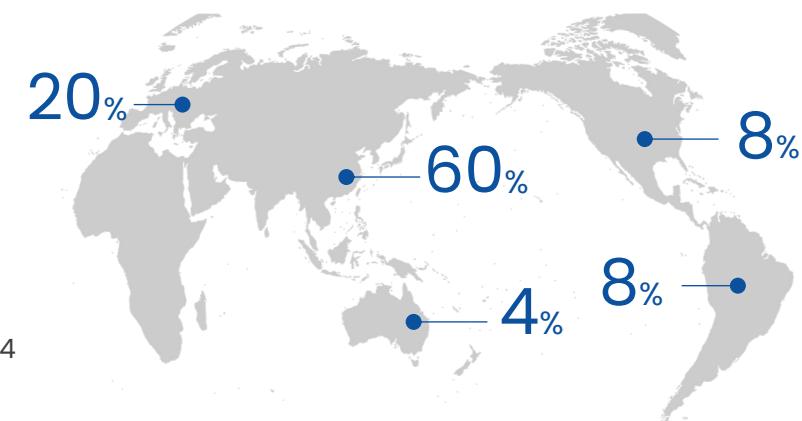
Dr. Jaffer A. Ajan
M.D Anderson
NCCN GC Chair

Dr. Ken Kato
NCCH



Primary Endpoints Key Milestone

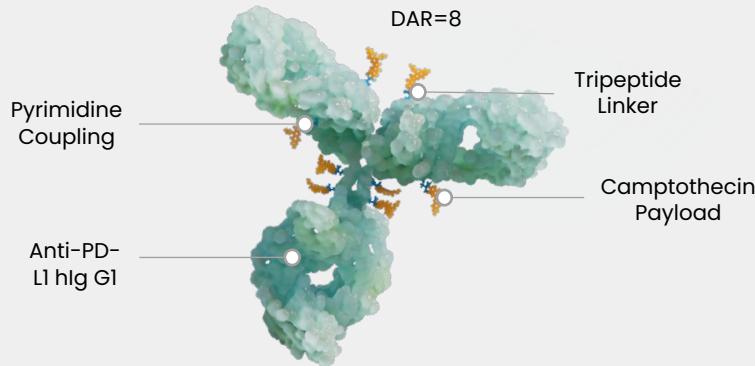
- PFS
- OS
- FPI: Nov 22, 2024



1. J Clin Oncol. 2025 43(suppl 4):abstr 440; 2. Lancet. 2023. 402(10418):2197; 3. J Clin Oncol 44, 2026 (suppl 2; abstr LBA285); 4. Yelena Y J.2024 ESMO.

HLX43 (PD-L1 ADC): High Efficacy, Low Toxicity, and IO Functionality

HLX43 (PD-L1 ADC)



500+

Patients Enrolled
(Solid Tumor)

>60%

Patients with NSCLC

Mechanism of Action

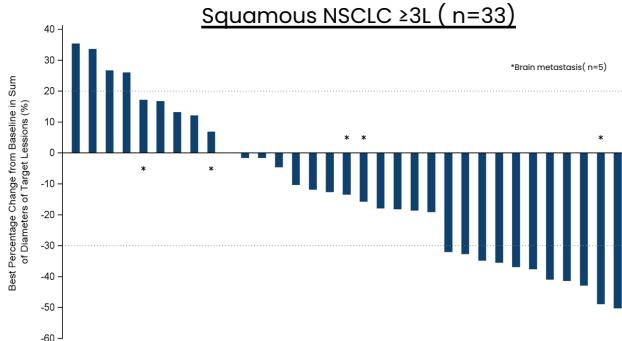
- Receptor-mediated internalization
- Bystander effect via payload release in TME, mediated by metalloproteinases and cysteine proteases
- Immuno-Oncology effects

Pan-Tumor Efficacy

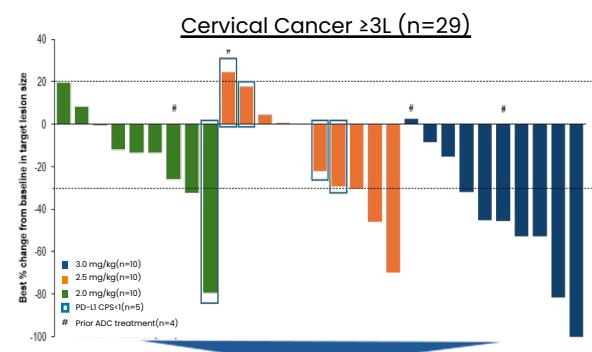
- Broad antitumor activity across multiple tumor types
- Activity independent of PD-L1 expression status

Safety Profile

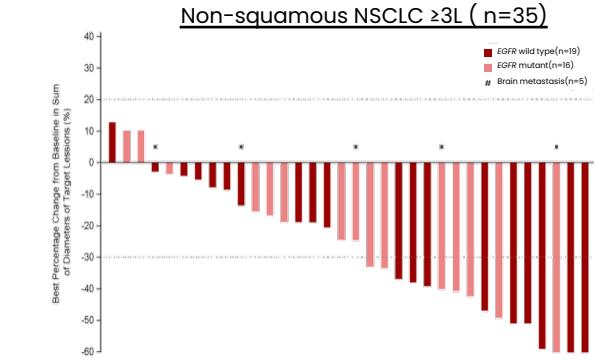
- Manageable hematologic toxicities with low incidence of thrombocytopenia



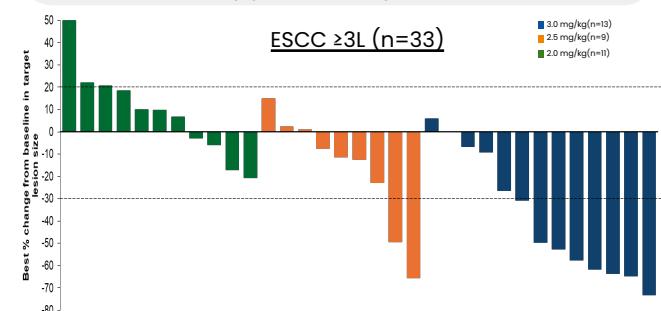
- 100% chemotherapy-refractory, 100% IO refractory, $\geq 3L$ (median)
- Squamous (2.0 mg/kg) ORR: 33.3%
- Docetaxel failed ($\geq 3L$) ORR: 38.5%



- 100% chemotherapy-refractory, ~50% IO-refractory, $\geq 3L$ (median)
- Cervical cancer (3.0 mg/kg) ORR: 70%



- 100% chemotherapy-refractory, ~80% IO-refractory, $\geq 3L$ (median)
- Non-squamous (2.5 mg/kg): ORR 48.6%
- EGFR wild-type (100% IO- and chemotherapy-refractory): ORR 47.4%



- 100% chemotherapy-refractory, 100% IO-refractory, $\geq 3L$ (median)
- ESCC (3.0 mg/kg) ORR: 61.5%

HLX43 (PD-L1 ADC): A High Potential Pipeline-in-a-pill BIC

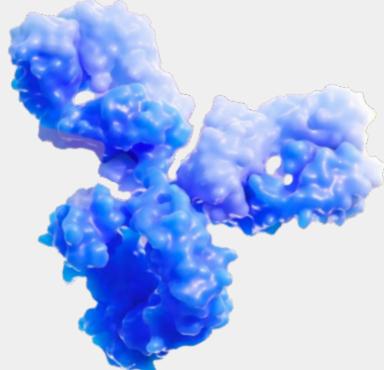
Tumor Type	Indication	Indication Cases*	LoT	Ph.1	Ph.2	Ph.3	Released Data
Lung	NSCLC	1411k	non-AGA 1L	Planned			
			Nsq non-AGA 2L	Planned			ORR: 47.4%
			Sq ≥2L	Planned			ORR: 33.3%
	SCLC	250k	1L				
Gastrointestinal	mCRC	1081k	2L				
	GC	559k	≥2L				
	ESCC	239k	2L				ORR: 61.5%
Breast	HR + BC	710k	2L				
			Neo-adjuvant				
			2L				
Others	TNBC	140k					
	HNSCC	225k	1L				
	NPC	56k	2L				
	CC	191k	2L				ORR: 70%

*Incident cases: new cases per year estimated from Globocan 2022 data in US+EU5+CN+JP

HLX07 (EGFR mAb): Enables Dual-target Synergy, Pioneering a New Path for 1L-treatment of EGFR-high-Expression sqNSCLC

HLX07 (EGFR)

Modified Humanized Monoclonal Antibody Targeting EGFR



Indication

First-line treatment of sqNSCLC with high EGFR expression (H-score ≥ 150)

*Approximately 89% of patients with sqNSCLC have high expression

- Lower immunogenicity; affinity similar to cetuximab
- High biological activity; possesses ADCC function
- Half-life is approximately 250 hours, markedly longer than cetuximab's half-life of ~112 hours

- Phase 2/3 MRCT versus SOC
- FPI planned for Q1 2026

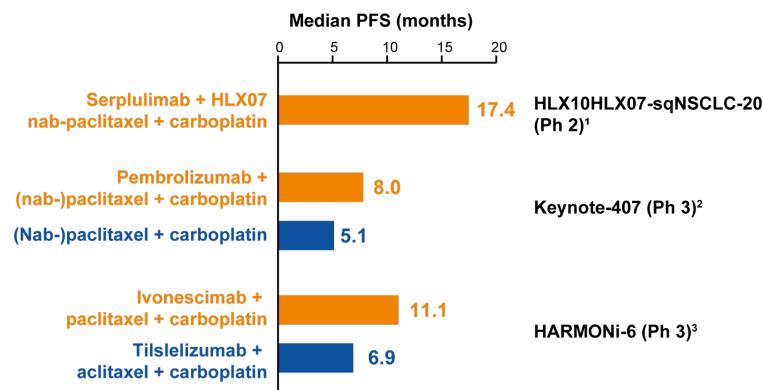
HLX10HLX07-sqNSCLC-201: a randomized, multicenter phase II dose-finding trial Positive Efficacy Signals (Median Follow-Up: 18.6 Months)

mPFS
17.4 months

DCR
100%

ORR
71.4%

mOS
Not Reached



Tumor Response Status

	Group A (n = 13)	Group B (n = 14)
ORR, % (95% CI)	69.2 (38.6–90.9)	71.4 (41.9–91.6)
DCR, % (95% CI)	92.3 (64.0–99.8)	100.0 (76.8–100.0)
Complete response, n (%)	0	0
Partial response, n (%)	9 (69.2)	10 (71.4)
Stable disease, n (%)	3 (23.1)	4 (28.6)
Progressive disease, n (%)	1 (7.7)	0
Not evaluable, n (%)	0	0

Significant Mechanistic Advantages of HLX07

Compared with cetuximab

- Lower immunogenicity
- Higher target affinity

- Extended half-life
- Longer administration interval
- Well-suited for combination with IO therapies

- Synergistic effects when combined with PD-1 inhibitors

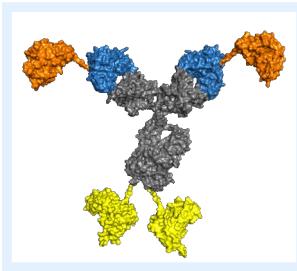
2026 Clinical Milestones

	Q1 2026	Q2 2026	Q3 2026	Q4 2026
Serplulimab (PD-1 mAb)	Regulatory Approval	Accelerated approval for Perioperative GC (CN)		
	Regulatory Approval	Expected Approval for nsqNSCLC & sqNSCLC (EU)		
	Regulatory Submission	ES-SCLC BLA filing (us)		
	Regulatory Submission	LS-SCLC BLA filing (us)		
	Study Progress	ES-SCLC Japan bridging study: Enrollment expected to complete, and primary endpoint met		
HLX22 (Novel HER2 mAb)	Data Readouts	HER2-low BC CN Ph2		
HLX43 (PD-L1 ADC)	Study Initiation	Global pivotal studies: 2L nsqNSCLC EGFRwt, ≥3L sqNSCLC, 2L sqNSCLC		
	Study Initiation	2 POC studies in BC: HR+ BC and TNBC		
	Data Publication	ASCO GI: ESCC ; ASCO: NSCLC, NPC ; ESMO: CC, OC		
	Data Readouts	Combination: preliminary POC data of HLX43 plus serplulimab ± HLX07 in NSCLC, SCLC, mCRC		
HLX07 (EGFR mAb)	Study Initiation	cscC Pivotal Ph2		
	Study Initiation	1L sqNSCLC Phase 2/3 MRCT		

Comprehensive World-class Technology Platforms as an Innovation Powerhouse

Next Generation IO

- PD-(L)1-based next-generation ICIs
- Addressing Immune Checkpoint Inhibitor Resistance
- Improving Clinical Response to ICIs



>7 assets

Hanjugator™ADC Platform

- Larger therapeutic window
- Overcome potential drug resistance
- Combination of toxins with multiple MOA



>12 assets

Immune Cell Engager

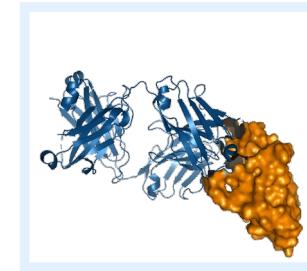
- Sustained, antigen-specific T-cell activation
- Enhanced efficacy in the tumor microenvironment (TME)
- Reduced risk of CRS



>5 assets

HAI Club platform

- De novo generation powered by Generative AI and LLMs
- Multi-parametric toxicity prediction for efficient screening
- Leveraging proprietary intelligence for druggability modeling



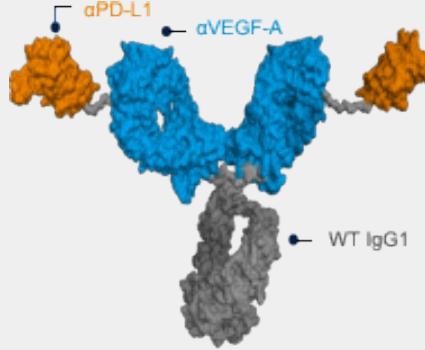
>40 INDs in the next 5 years

HLX37: PD-L1xVEGF bsAb, A Next-generation I/O Product After Serplulimab

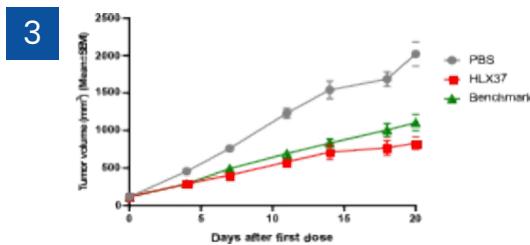
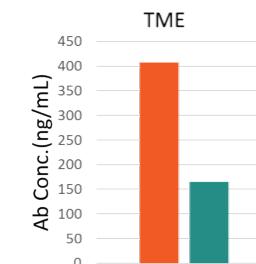
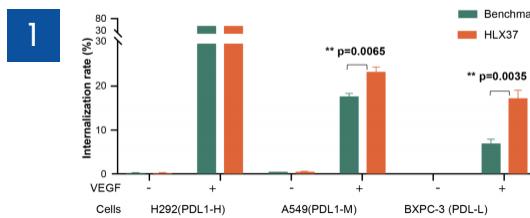
HLX97: A Potential Best-In-Class KAT6A/B Inhibitor

2025 IND

HLX37 PD-L1xVEGF bsAb

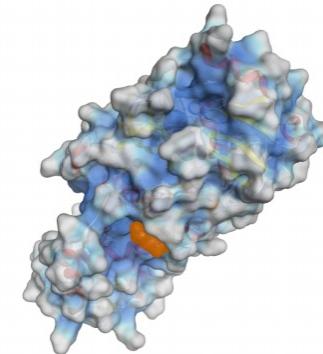


- High affinity for PD-L1; enhanced accumulation in the tumor microenvironment (TME)
- Favorable developability

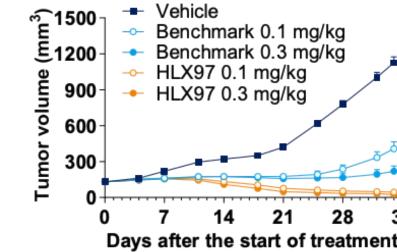


- Efficient PD-L1 internalization leading to enhanced T-cell activation
- Higher TME enrichment vs. combination therapy
- Superior efficacy vs. competitors in the A549 model

HLX97 KAT6A/B inhibitor



- Broad oncology applications including BrCa, CRPC, and NSCLC
- Superior in vitro and in vivo efficacy compared to competitors
- Unique PK profile mitigates accumulation and on-mechanism hematologic toxicity
- Favorable ADMET* profile



2

Model 1: ZR-75-1

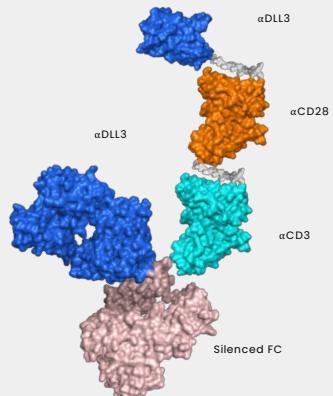
Treatment	Dose (mpk)	TGI (%)	↓WBC# (%)	↓Lym# (%)	Dose (mpk)	TGI (%)	↓WBC# (%)	↓Lym# (%)	Dose (mpk)	TGI (%)	↓WBC# (%)	↓Lym# (%)
Benchmark	0.1	72	19	3	0.3	91	31	24	1	19	58	47
HLX97	0.1	109	15	3	0.3	111	23	15	1	61	72	10

HLX3901: The Best-in-class DLL3 TCE

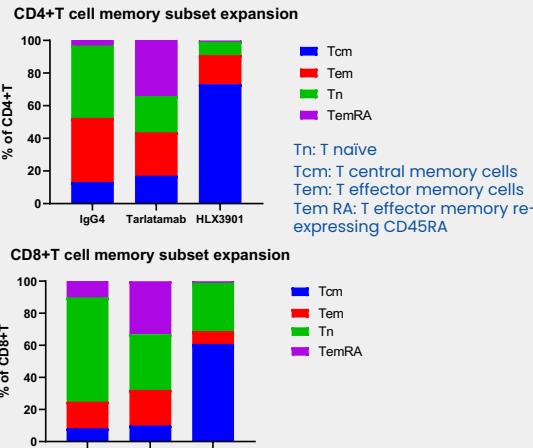
HLX316: A Novel, First-in-class anti-B7H3 Sialidase or Solid Tumors

2025 IND

HLX3901 DLL3x DLL3x CD3x CD28

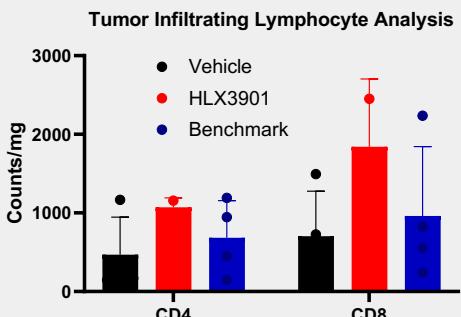


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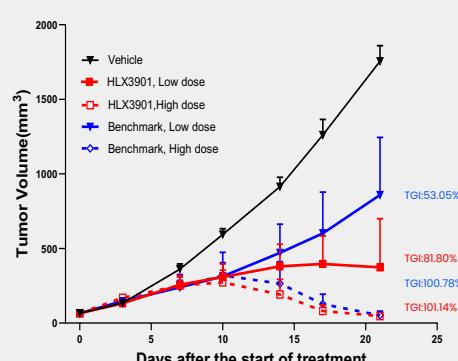


Key Strengths

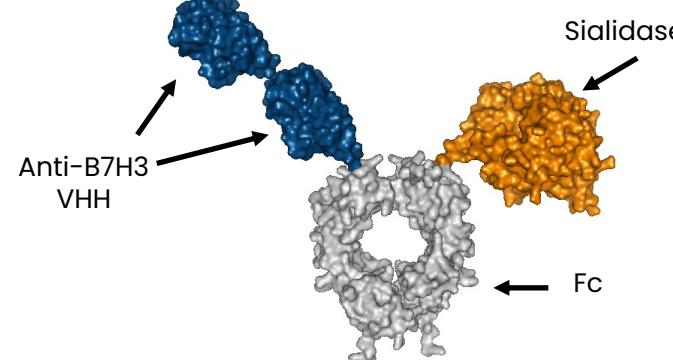
- Longer persistence of activated T cells via secondary T-cell signaling.
- Greater efficacy in solid tumor treatment.



2



HLX316 Anti-B7H3 Sialidase



- Sialidase from Palleon's EAGLE platform
- Anti-B7H3 VHH engineered by Henlius.
- Novel and first-in-class (FIC)

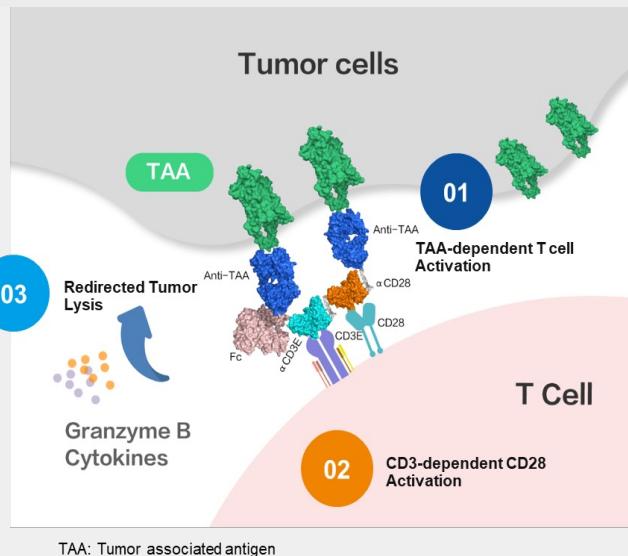
- B7H3 (CD276): an emerging TAA for cancer therapy.
- Hypersialylation: excessive sialic acid on tumor cells suppresses tumor-related immune responses.
- HLX316: an Fc-fused, B7H3-targeted sialidase that removes tumor sialic acid to enhance immune response.
- In collaboration with Palleon Pharmaceuticals

HLX3902: A FIC STEAP1xCD3xCD28 TCE for the Treatment of Prostate Cancer

2026 IND

HLX3902 STEAP1xCD3xCD28 TCE

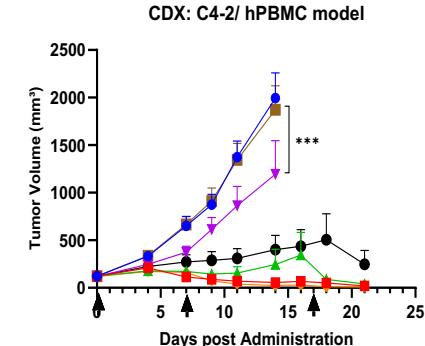
- CD28 as a co-stimulation signal not only produces a more rapid anti-tumor effect but also maintains T cell activation for a longer period of time.
- Addressing the problem of CD28 toxicity through the design of special epitopes and cis-binding design in TCE.



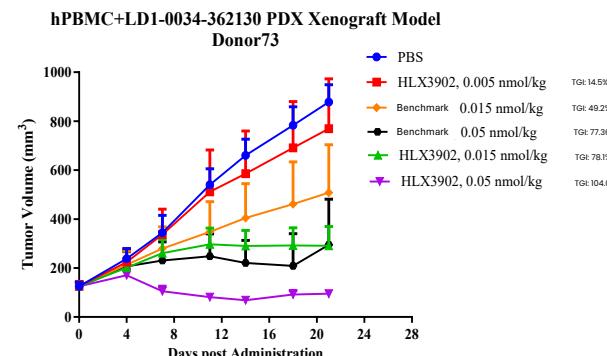
Key Strengths:

- Longer persistence of activated T cell with secondary T cell signaling
- Greater efficacy in solid tumor treatment
- Improved therapeutic window

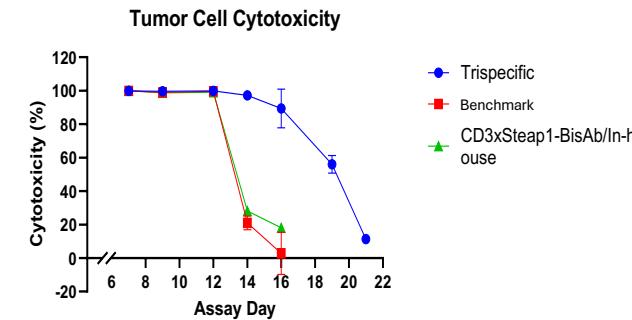
HLX3902 exhibited superior antitumor activity, increased T-cell infiltration and persistence in TME over Benchmark



HLX3902 exhibited superior antitumor activity over Benchmark in Abiraterone Resistant model



HLX3902 exhibited more sustained cytotoxicity than Benchmark



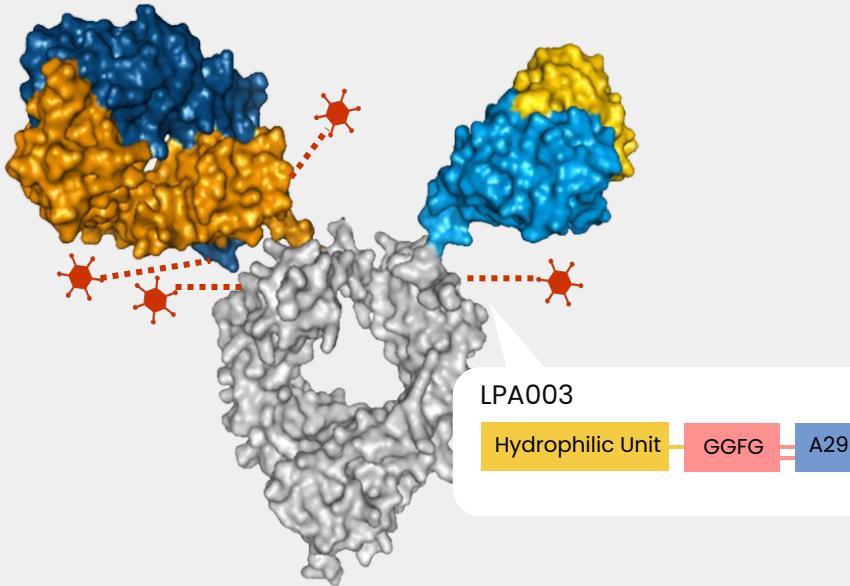
HLX48: A safer and more effective EGFRxcMET ADC for NSCLC and CRC

2026 IND

HLX48 (EGFRxcMET ADC)

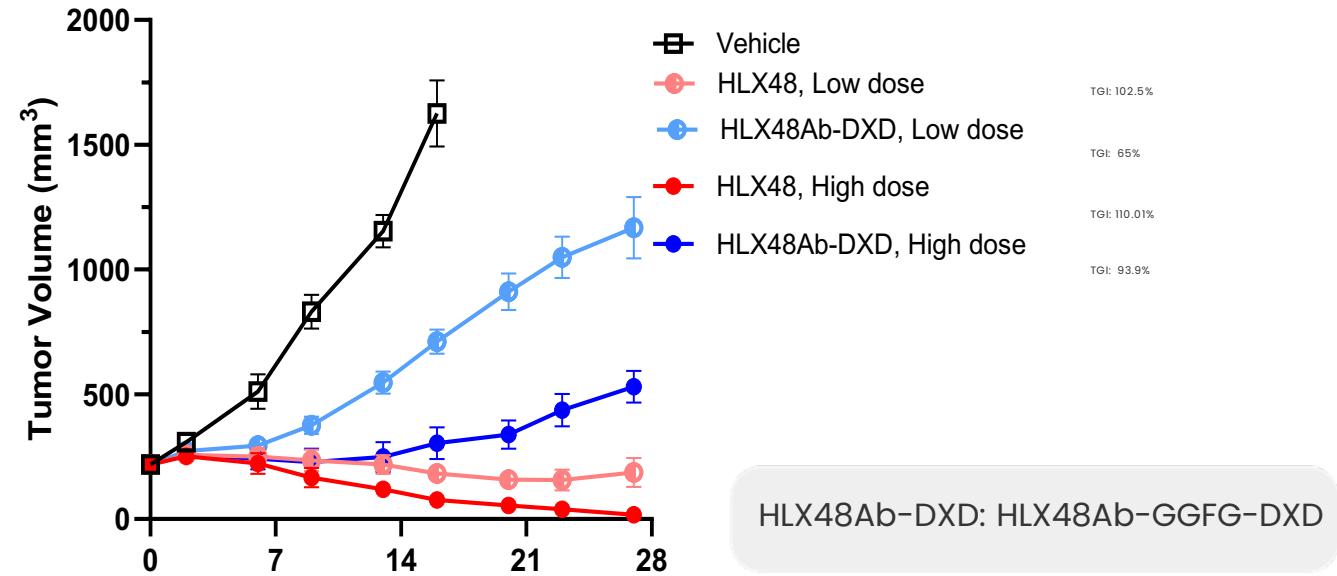
Anti-cMET

Anti-EGFR



HLX48 ADC is significantly more efficacious than HLX48-GGFG-DXD

SW48 CRC/CDX model



Key Strengths:

- Improved therapeutic window to maximize antibody function
- A stronger bystander effect, addressing the issue of tumor heterogeneity

HNSTD of HLX48 is 60mg/kg

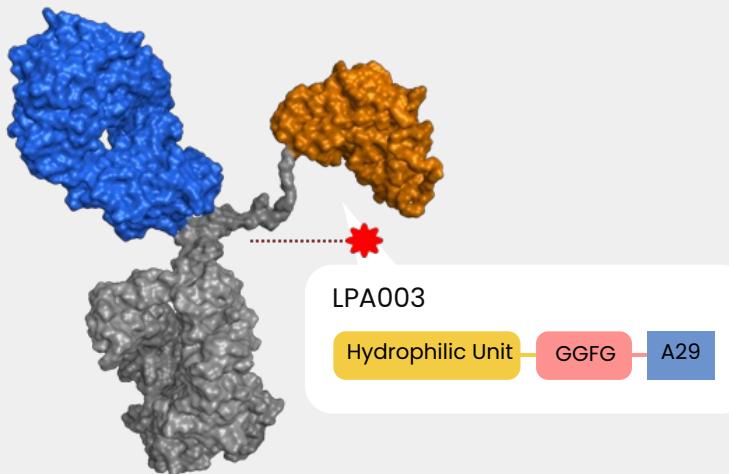
HLX49: A BIC HER2xHER2 Novel Bi-paratopic ADC for treatment of BC and GC

2026 IND

HLX49 (HER2xHER2 ADC)

HLX22

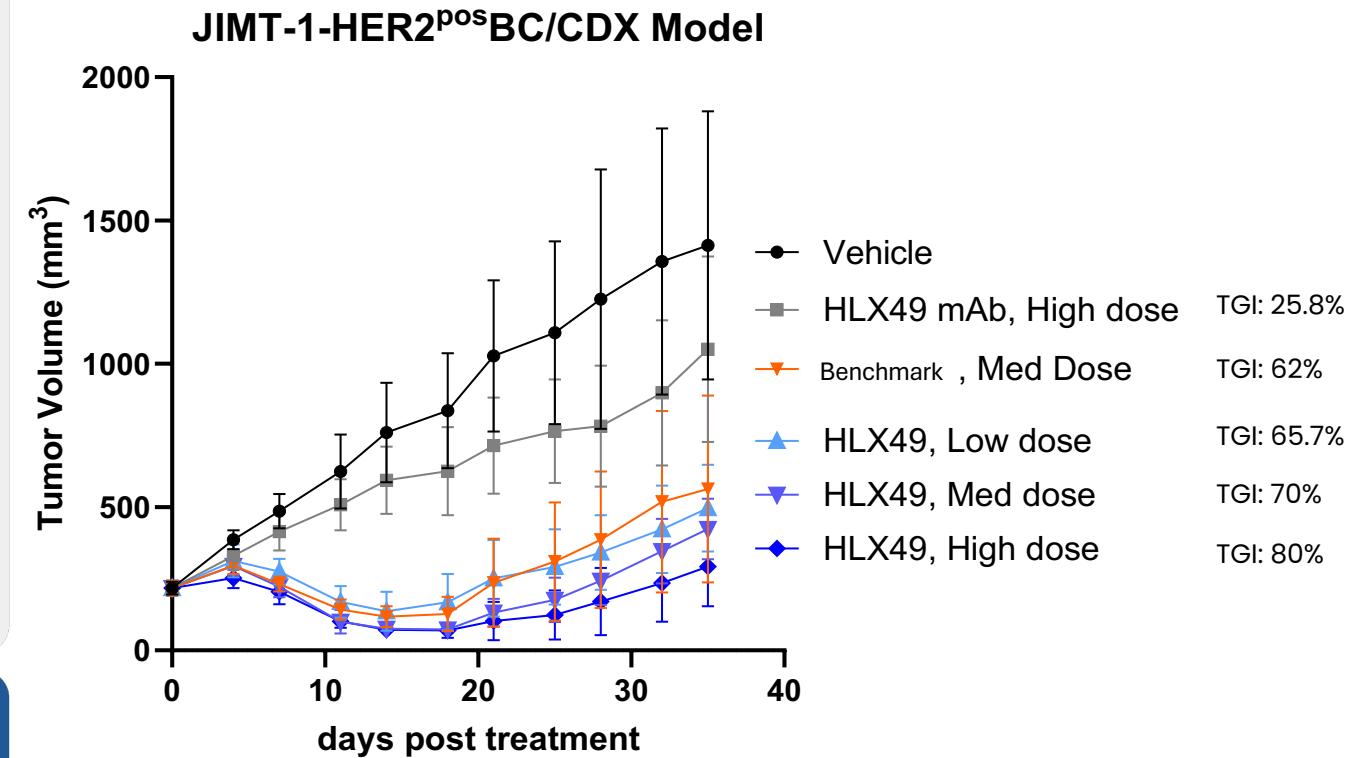
HLX02



Key Strengths:

- Higher and safer tolerance, maximizing the function of antibodies
- The special epitope of HLX22 enhances the endocytosis of HER2/HER2 and HER2/EGFR, and strengthens the inhibitory activity

HLX49 showed better efficacy than Benchmark



Preclinical Pipeline

PCC-to-IND Stage

2025 IND
 2026 IND
 FIC
 BIC
 FAST-FOLLOW

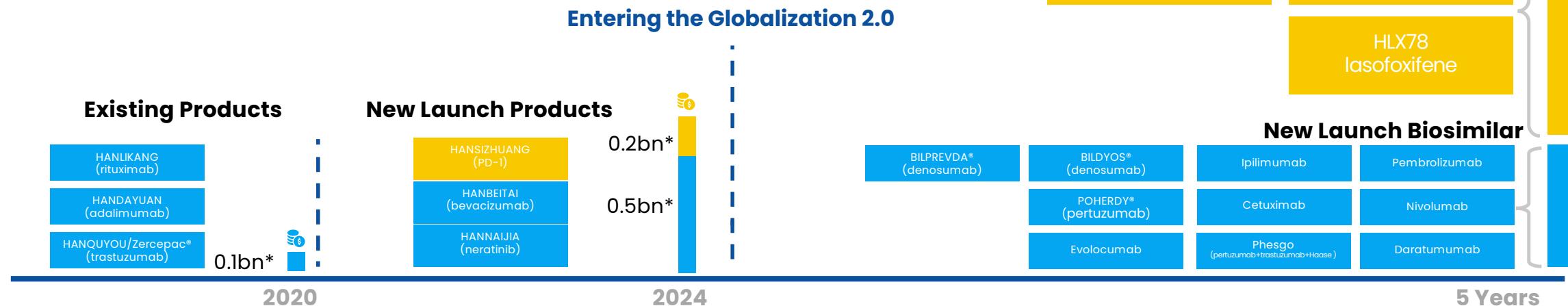
Molecule	Indication	Novelty
1 PD-L1xVEGF BsAb	Solid tumor	FAST-FOLLOW
2 DLL3xDLL3xCD3xCD28 TCE	SCLC	BIC
3 B7H3-sialidase fusion protein	Solid tumor	FIC
4 KAT6 A/B inhibitor	BC	BIC
5 EGFRxMet BsADC	NSCLC, CRC	BIC
6 STEAP1xCD3xCD28 TCE	Prostate cancer	BIC
7 LIV1 ADC	BC	BIC
8 CDH17 ADC	Solid tumor	BIC
9 Her2xHer2 ADC	BC, GC	BIC
10 ALPP/ALPPL2 ADC	Solid tumor	FIC
11 ADAM9 ADC	Solid tumor	FIC
12 PD1xIL2 fusion protein	Solid tumor	BIC
13 IL-1R3 mAb	I&I disease	BIC

Strong growth trajectory in the next 5 years to drive global expansion

- Entered Europe in 2020 and the U.S. in 2025
- The biosimilar pipeline fuels innovation with robust cash flow
- In the coming years, more than 10 products will be launched globally

Biosimilar

Innovative Drugs



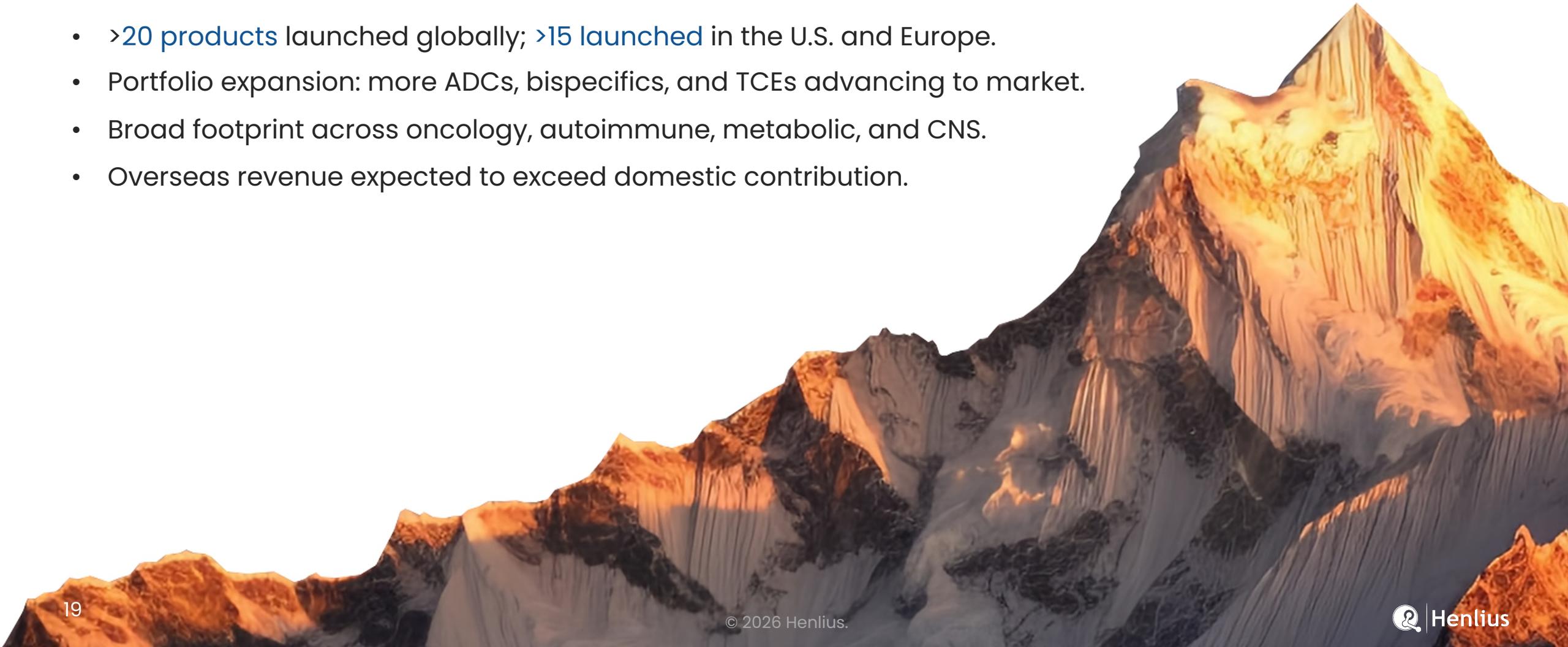
*Product revenue: product sales in US dollars (Excluding upfront payments and milestones)

Exchange rate: USD/RMB 7.1

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Henlius 2030 Vision: *A Global Biopharma Company*

- >20 products launched globally; >15 launched in the U.S. and Europe.
- Portfolio expansion: more ADCs, bispecifics, and TCEs advancing to market.
- Broad footprint across oncology, autoimmune, metabolic, and CNS.
- Overseas revenue expected to exceed domestic contribution.



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Reliable Quality
Affordable Innovation

