

FORGING THE FUTURE

开创未来

国际肺癌前沿及创新论坛

INTERNATIONAL SUMMIT ON FRONTIERS AND INNOVATIONS IN LUNG CANCER

中国创新升级 助力肿瘤全球化防控

Innovating from China: Powering the next wave of global cancer care

朱俊 博士 Dr. Jason Zhu

复宏汉霖执行董事，首席执行官 Henlius Executive Director and Chief Executive Officer

Lung Cancer—The NO.1 cancer killer globally



Non-Small Cell Lung Cancer (NSCLC)

Accounts for approximately **85%** and originates from larger cells in the lungs.

Small Cell Lung Cancer (SCLC)

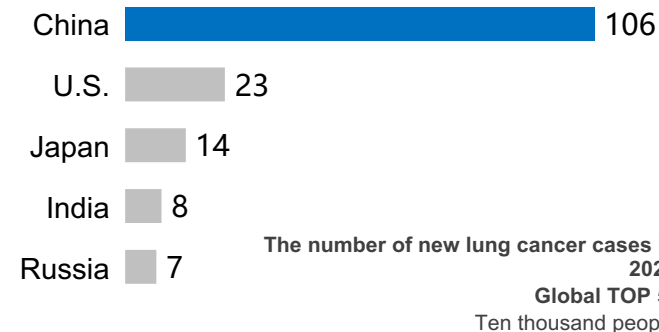
Accounts for approximately **15%** of lung cancer cases and is more invasive with faster growth.

Annual global new cases

~ **2.4 million** people¹

The **most common** cancer worldwide

China's new lung cancer cases far exceed other countries



Annual global mortality

~ **1.8 million** people¹

#1 Cancer killer for 30 Years,
~**18.7%** mortality rate

Global five-year survival has improved but remains suboptimal

China 29%
NCC 2019~2021

UK/DE 17%/21%
UK 2018² / DE 2020³

U.S. 28%
SEER 2017

Japan 35%
Ganjoho 2009-2011

1. World Health Organization. Cancer. <https://www.who.int/news-room/fact-sheets/detail/cancer>
2. Trends over 48 years in a one-number index of survival for all cancers combined, England and Wales (1971–2018): a population-based registry study Coleman, Michel P. et al. The Lancet Regional Health - Europe, Volume 56, 101385
3. https://www.krebsdaten.de/Krebs/EN/Content/Cancer_sites/Lung_cancer/lung_cancer_node.html

A Biopharma Company from China to the World

Benefiting **900,000+** Patients

9 marketed products

6 products approved for marketing overseas

~ 60 approved countries



Therapeutic Area



Tumor



Autoimmune



Ophthalmology

Henlius Brings Hope to Lung Cancer Patients Worldwide

100,000+

lung cancer patients have benefited from treatment with Henlius' products



HANSIZHUANG®-Serplulimab

- Launched in ~40 countries
- First one anti-PD-1 approved globally for 1st Line ES-SCLC
- Indicated for sq/ns-NSCLC, ES-SCLC and ESCC



HANBEITAI®-Bevacizumab

- The 4th independently developed product by Henlius
- Indicated for advanced/metastatic, or recurrent NSCLC

FORGING THE FUTURE

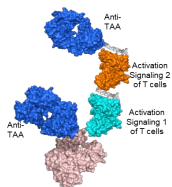
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Henlius' international innovation capabilities span from R&D to production

Cutting-edge Innovation and Global R&D Capabilities

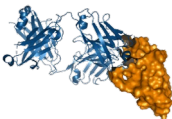
Three differentiated Technology Platforms with Global Competitiveness



Tri-specific T cell engager



Hanjugator™ ADC platform



HAI Club Platform

Global Clinical Development Operations and Regulatory Development

Globally Integrated Clinical Operations and Development Capabilities

20+ countries **1,000+** clinical research centers
10,000+ patients (over 1,700 ex-China)
Main countries/regions (China, the United States, Japan, Australia, etc.)
An in-house global clinical team of ~500 people

A Global Regulatory Affairs team with In-depth Knowledge of Global Regulatory Approval Pathways

9 launched products
6 approved overseas
4 launched in U.S. & Europe
Over 140 clinical trial approvals obtained across multiple countries and regions, including China, the US, Europe, Japan, and Australia.

International Leading Capabilities on Manufacturing and Quality Management

Three Plants:
Commercial GMP production exceeds 1,150 batches



Certified to GMP Standards in Multiple Countries and Regions
An International Standard QMS Throughout the Product Lifecycle

国家药品监督管理局
National Medical Products Administration



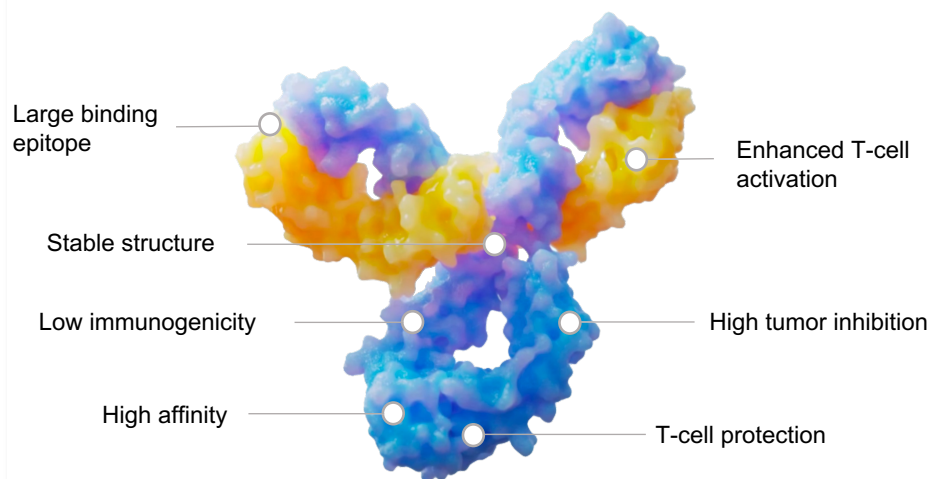
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INTERNATIONAL SUMMIT ON FRONTIERS AND INNOVATIONS IN LUNG CANCER

HLX10: World's first anti-PD-1 mAb for the first-line treatment of SCLC

HLX10 (PD-1) Serplulimab



Launched



Esophageal squamous cell carcinoma



Lung cancer

Pipeline



Colorectal cancer



Gastric cancer

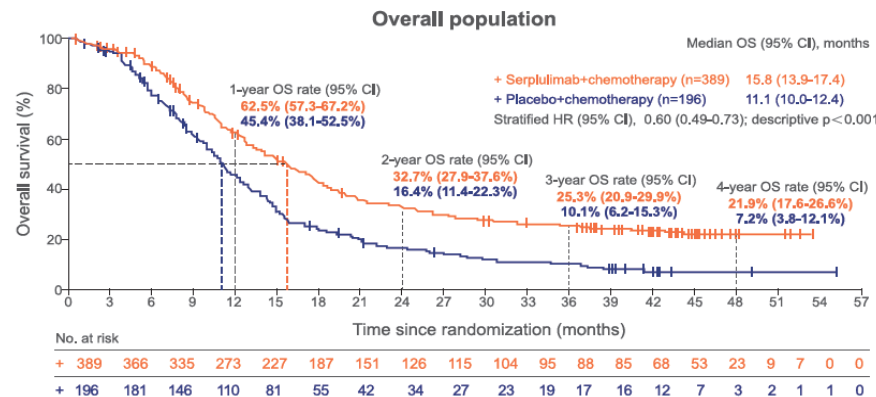
- ASTRUM-005 study long-term follow-up data, first release of 4-year OS rate: 21.9%
- LS-SCLC and colorectal cancer have completed patient enrollment
- ES-SCLC will submit to the US FDA for marketing application by 2026
- First patient dosed in Japan for small cell lung cancer bridge study
- Gastric cancer surgery phase clinical trial achieved positive results, supporting early submission, ushering in the era of chemo-free therapy

The world's first anti-PD-1 monoclonal antibody approved for first-line treatment of SCLC

2025 ASCO[®]
ANNUAL MEETING

Long-term results and patient-reported outcomes from the ASTRUM-005 study, first published 4-year OS rate: 21.9%

By the data cutoff of May 7, 2024, the median follow-up duration was 42.4 months.



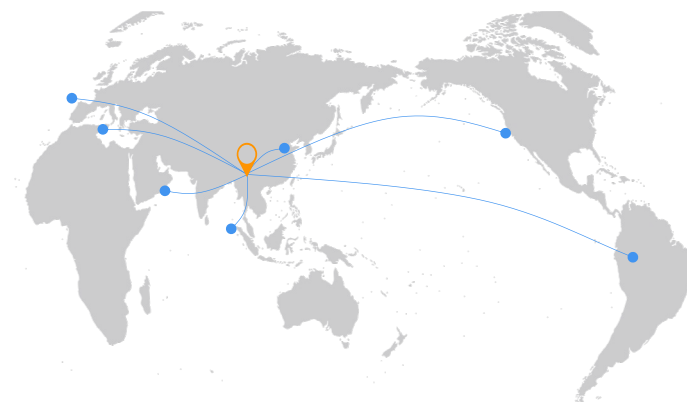
From East to West, the global launch plan will continue to advance patients worldwide.

Differentiated Indications:

- Positive results have been achieved in the perioperative clinical trial for gastric cancer, which is expected to change the treatment landscape
- Patient enrollment has been completed for the clinical trials of LS-SCLC and colorectal cancer

New Markets to Explore:

- U.S.: For ES-SCLC, >100 clinical sites have been activated, all enrollment has been completed; FDA BLA submission is planned in 2026 for LS/ES-SCLC
- Japan: Completed first patient dose in the Japanese bridging study for SCLC



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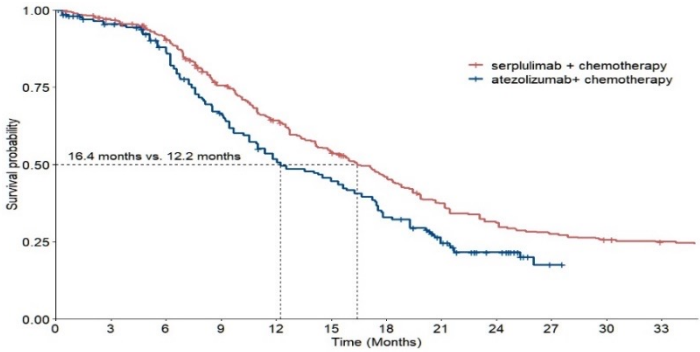
INTERNATIONAL SUMMIT ON FRONTIERS AND INNOVATIONS IN LUNG CANCER

Serplulimab gains EU orphan drug designation with demonstrated clinical benefit

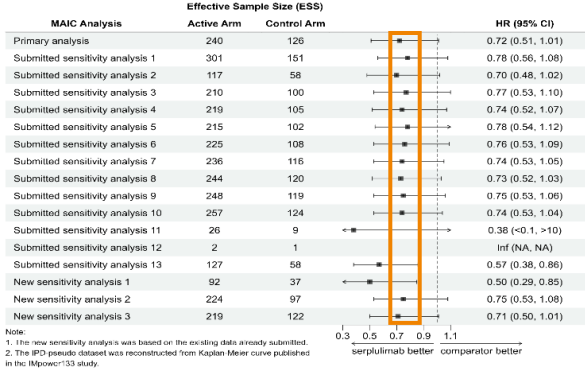
ASTRUM-005 vs. IMpower133

MAIC	
mPFS	5.5m vs. 5.2m
HR (95% CI)	0.73 (0.53, 0.99)
mOS	16.4m vs. 12.2m
HR (95% CI)	0.72 (0.51, 1.01)

Both mOS and mPFS demonstrated superiority over the approved therapies of Atezolizumab+chemo and Durvalumab+chemo.

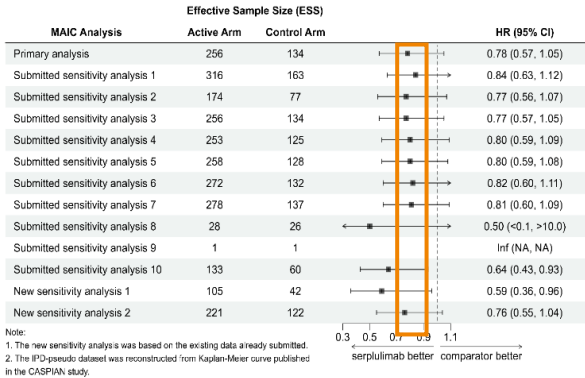
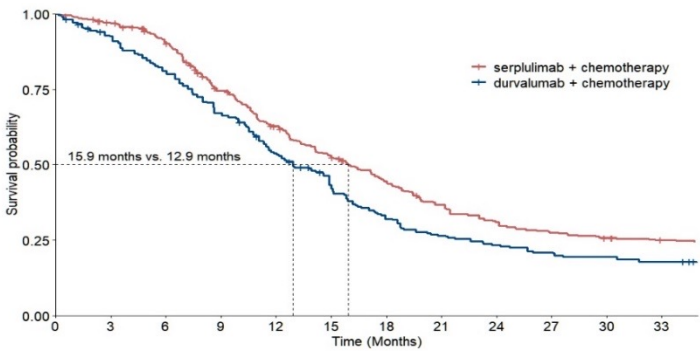


The highly consistent sensitivity analyses further confirm the robust and reliable clinical benefit of Serplulimab in treating ES-SCLC



ASTRUM-005 vs CASPIAN

MAIC	
mPFS	5.5m vs. 5.1m
HR (95% CI)	0.70 (0.53, 0.94)
mOS	15.9m vs. 12.9m
HR (95% CI)	0.78 (0.57, 1.05)



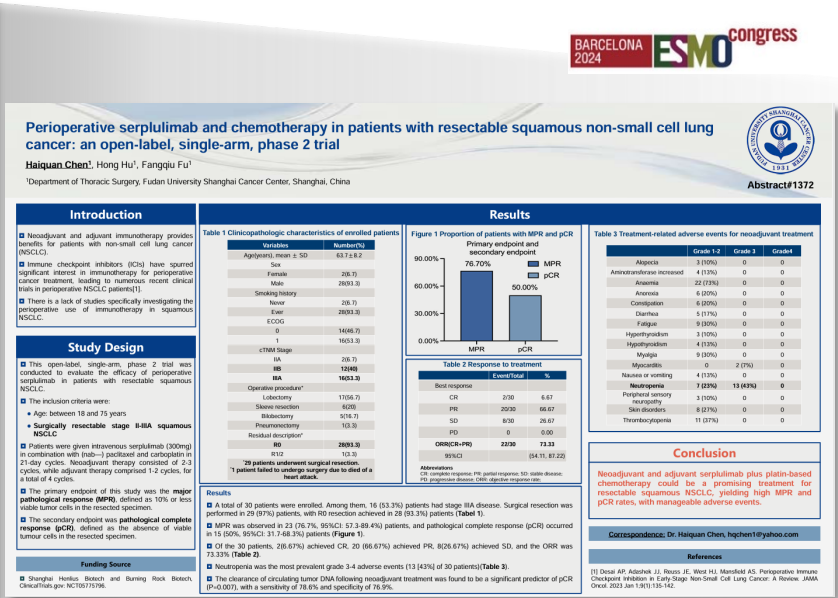
HLX10 (Serplulimab) granted orphan drug designation in the US & EU for SCLC

- Serplulimab: ASTRUM-005 试验个体患者数据 (IPD, 数据截止日期: 2022.06.13)
- Atezolizumab: IMpower133 试验公开汇总数据 (SV, Liu et al. J Clin Oncol, 2021)
- Durvalumab: CASPIAN 试验公开汇总数据 (Paz-Ares L, et al. ESMO Open, 2022)

Serplulimab is dedicated to bringing long-term survival benefits to more lung cancer patients

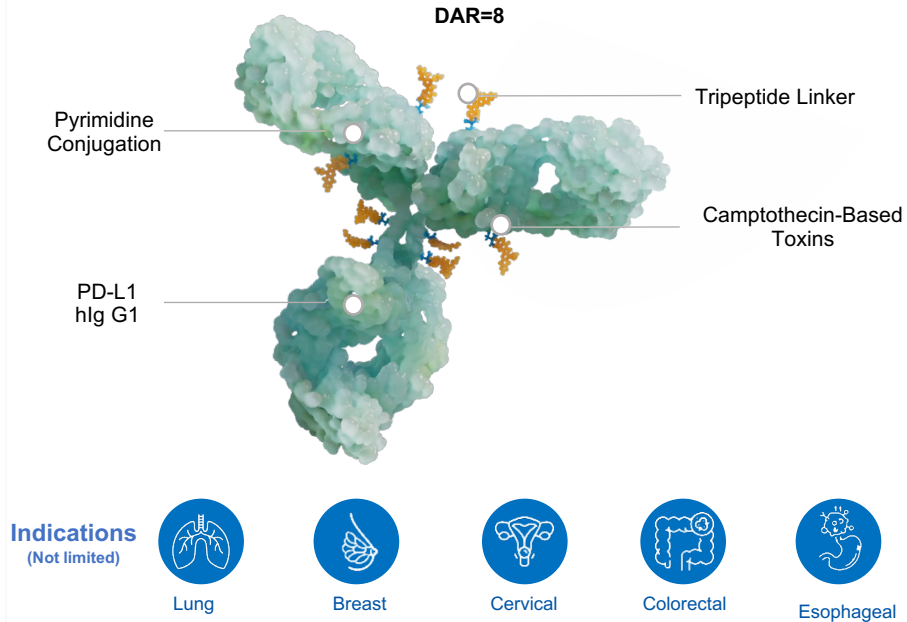
Globally, there are ~744K new cases of sqNSCLC annually, with stage II-IIIA operable patients accounting for about 20% (~148K individuals). HLX10IT21 in perioperative sqNSCLC yielded striking rates of **50% pCR and 76.7% MPR**, a marked improvement over prior regimens, enhancing hope for patient survival.

	Checkmate 816	Checkmate 77T	KEYNOTE-671	AEGEAN	Neotorch	RATIONALE 315	NADIM II	HLX10IT21
Study drug	Nivolumab	Nivolumab	Pembrolizumab	Durvalumab	Toripalimab	Tislelizumab	Nivolumab	Serplulimab
Study Phase	III	III	III	III	III	III	II (IIT)	II (IIT)
Study design	3 cycles of neo-adjuvant + Adjuvant CT/RT	4 cycles of neo-adjuvant + 1y IO mono adjuvant	4 cycles of neo-adjuvant + 13 cycle IO mono adjuvant	4 cycles of neo-adjuvant + 12 cycle IO mono adjuvant	3 cycles of neo-adjuvant + 1 cycle IO mono adjuvant	3-4 cycles of neo-adjuvant + 8 cycle IO mono adjuvant (Q6W)	3 cycles of neo-adjuvant IO comb CT + 1-2 cycle adjuvant IO mono adjuvant	2-3 cycles of neo-adjuvant IO comb CT+ 1-2 cycle adjuvant IO comb CT
Patient type	IB-IIIA (AJCC v7.)	IIA-IIIB(N2) (AJCC v8.)	Resectable Stage II, IIIA, and IIIB (N2)	IIA-IIIB	IIIA/B (IIIA:67.3%)	II-IIIA	Resectable Stage IIIA-IIIB NSCLC	II-IIIA sqNSCLC
III%vsII%	63.1% vs 36%	64% vs 35%	70.3% vs 29.7%	71.3% vs 28.4%	100.00%	58.4% vs 48.2%	--	53.3% vs 46.7%
Primary endpoint	pCR; EFS	EFS	EFS;OS	pCR;EFS	EFS;MPR	EFS;MPR/pCR	ITT: pCR	MPR; pCR
Underwent curative surgery	83% vs 75%	78% vs 77%	98.5% vs 95.3%	77.6% vs 76.7%	82.2% vs 73.3%	84.1% vs 76.2%	--	96.6%
Enrollment	358	461	797	802	404	453	86	30
sq vs. nsq	48.6% vs 51%	51% vs 49%	43.1% vs 59.6%	46.2% vs 53.6%	77.7% vs 22.3%	79.2% vs 19.9%	--	100% vs 0%
pCR%	24.0%	25.3%	18.1%	17.2%	24.8%	40.7%	37%	50%
MPR%	36.90%	35.40%	30.20%	33.30%	48.50%	56.20%	53%	76.7%
irAE%	--	---	25.3% vs 10.5%	23.5%vs 9.8%	42.1%vs 22.8%	unpublished	unpublished	--



HLX43: a PD-L1 ADC with high efficacy, low toxicity, and I/O function, demonstrating prominent broad-spectrum anti-tumor potential

HLX43 (PD-L1 ADC)



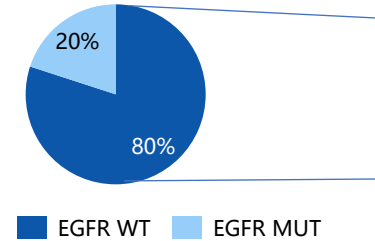
- It combines the dual efficacy of ADC and immunotherapy (I/O), and is expected to cover the entire patient population (not limited to PD-L1-positive patients)
- The Phase I clinical trial has demonstrated outstanding preliminary efficacy, with particularly remarkable performance in non-small cell lung cancer (NSCLC) and thymic squamous cell carcinoma
- It has obtained approvals in China, the United States, Australia, and Japan to initiate a Phase II international multi-center clinical trial (MRCT) for advanced NSCLC, making it the first domestically developed PD-L1 ADC to enter Phase II
- It is simultaneously advancing the development for multiple tumor types and actively exploring a variety of combination regimens, including combination therapy with Serplumab.
- Granted ODD by the U.S. FDA in Thymic Epithelial Tumors (TETs)



NSCLC

Annual Global New Cases

~2.0 mil^{1,2}



EGFR wild-type:
Large patient population and significant unmet clinical needs.

Multiple indications in clinical development. ★ With positive result

HER2- BC 1960k	CRC 1930k	GC 968k	CC 661k	TC (Rare Disease) 10~30k
PDAC 511k	ESCC 380k	OC 324k	HNSCC 824k	NPC 120k

HLX43 was well-tolerated across different doses, with no new safety signals observed. It demonstrated encouraging preliminary efficacy in patients with advanced solid tumors (including NSCLC and TSCC) who had failed previous standard treatments

A Broad Therapeutic Effects

Outstanding efficacy across multiple tumor types, including TSCC, heavily treated NSCLC

B Not Dependent on Biomarkers

It has demonstrated efficacy in a variety of NSCLC

- Regardless of the presence or absence of EGFR mutations
- Regardless of the presence or absence of brain metastases.

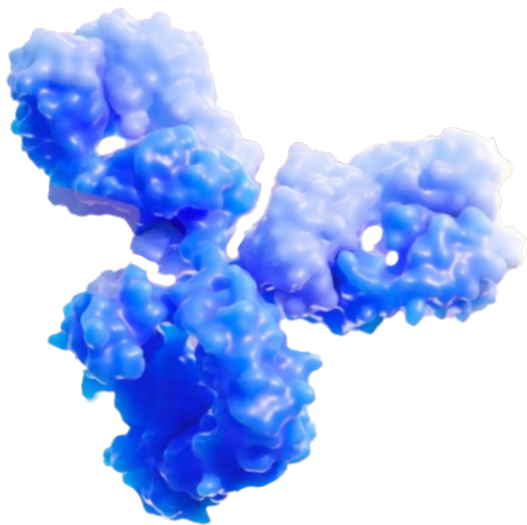
C Favorable Safety Profile

Low hematologic toxicity (grade ≥3 TRAE are rare), which provides strong support for its future expansion to first-line treatment and combination regimens

HLX07 enables dual-target synergy, pioneering a new path for 1L-treatment of EGFR-high-expression sqNSCLC

HLX07 (EGFR)

Modified Humanized Monoclonal Antibody Targeting EGFR



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

Indication

*Approximately 89% of patients with sqNSCLC have high expression

- Compared with cetuximab, this product exhibits lower immunogenicity and better target affinity.
- Through Fc region engineering, HLX07 significantly extends the product's half-life; its 3-week administration frequency makes it more suitable for clinical combination with immunology products.
- Preclinical studies have shown that HLX07 has superior biological activity, can significantly inhibit the growth of tumor cells in different tumor models, and demonstrates strong synergy with the H-drug

The HLX10HLX07-sqNSCLC-201 study is a randomized, multicenter phase II dose-finding trial consisting of four parts, which evaluates multiple combinations of HLX07 (at different doses), Serplulimab, and chemotherapy. According to the updated data, the combination of HLX07, Serplulimab, and chemotherapy has demonstrated significant anti-tumor activity and durable efficacy in patients with EGFR-high-expression sqNSCLC

Positive Efficacy Signals (Median Follow-Up: 18.6 Months)

mPFS	DCR	ORR	mOS
17.4 months	100%	71.4%	Not Reached
VS.	8.0m Pembrolizumab KEYNOTE-407	10.1m Benmelstobart TQ82560-III-12	11.1m Ivonescimab HARMONI-6

Favorable Safety Profile

- Common adverse events are controllable
- No new safety signals observed

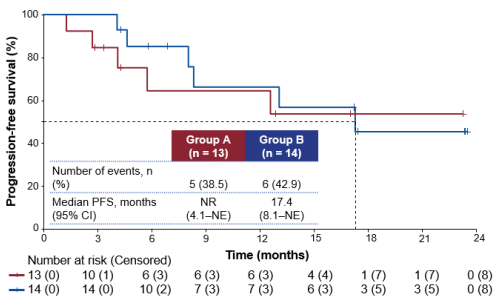
Significant Mechanistic Advantages

- Compared with cetuximab: lower immunogenicity and better target affinity
- Extended half-life and longer administration interval, making it more suitable for combination with I/O agents
- Demonstrated synergistic effects when combined with PD-1 inhibitors across different tumor models

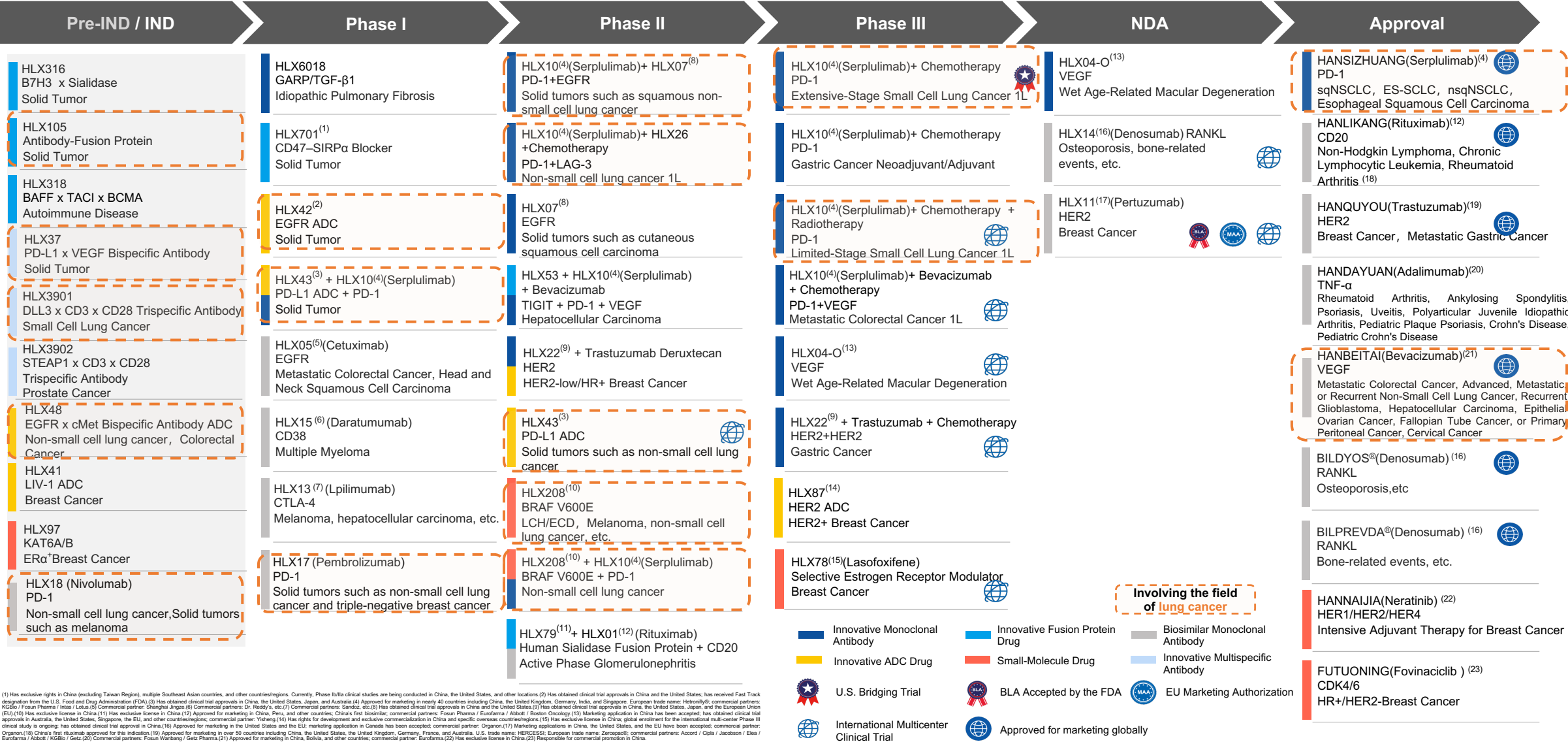
Tumor Response Status

	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

PFS Results Assessed by BICR (RECIST v1.1)



Henlius Pipeline: Poised for Multiple Breakthroughs in Lung Cancer



(1) Has exclusive rights in China (excluding Taiwan Region), multiple Southeast Asian countries, and other countries/regions. Currently, Phase I/IIa clinical studies are being conducted in China, the United States, and other locations. (2) Has obtained clinical trial approvals in China and the United States; has received Fast Track designation from the U.S. Food and Drug Administration (FDA). (3) Has obtained clinical trial approvals in China, the United States, Japan, and Australia. (4) Approved for marketing in nearly 40 countries including China, the United Kingdom, Germany, India, and Singapore. European trade name: Heliolymab; commercial partners: KGBio / Fosun Pharma / Intas / Lotus. (5) Commercial partner: Shanghai Jingze. (6) Commercial partners: Dr. Reddy's, etc. (7) Has obtained clinical trial approvals in China and the United States. (8) Has obtained clinical trial approvals in China, the United States, Japan, and the European Union (EU). (9) Has exclusive license in China. (10) Has exclusive license in China. (11) Has exclusive license in China. (12) Approved for marketing in China, Peru, and other countries; China's first biosimilar; commercial partners: Fosun Pharma / Eurofarma / Abbott / Boston Oncology. (13) Marketing application in China has been accepted; has obtained clinical trial approvals in Australia, the United States, Singapore, the EU, and other countries/regions; commercial partner: Yisheng. (14) Has rights for development and exclusive commercialization in China and specific overseas countries/regions. (15) Has exclusive license in China, global enrollment for the international multi-center Phase III clinical study is ongoing; has obtained clinical trial approval in China. (16) Approved for marketing in the United States and the EU; marketing application in Canada has been accepted; commercial partner: Organon. (17) Marketing applications in China, the United States, and the EU have been accepted; commercial partner: Organon. (18) China's first rituximab approved for this indication. (19) Approved for marketing in over 50 countries including China, the United States, the United Kingdom, Germany, France, and Australia. U.S. trade name: HERCEPTIN; European trade name: Zentopos; commercial partners: Accord / Cipla / Janssen / Eisai / Eurofarma / Abbott / KGBio / Getz. (20) Commercial partners: Fosun Wanbang / Getz Pharma. (21) Approved for marketing in China, Bolivia, and other countries; commercial partner: Eurofarma. (22) Has exclusive license in China. (23) Responsible for commercial promotion in China.

The background features a dark blue gradient with dynamic, flowing light patterns in shades of blue and purple. These patterns resemble energy waves or smoke, creating a sense of movement and depth. The word "THANKS" is centered in a bold, white, sans-serif font, standing out against the vibrant, abstract backdrop.

THANKS

科学引领未来： 早期肺癌创新管线布局与展望

Science Leading the Future: Early-Stage Lung Cancer Pipeline and Strategic Outlook

袁纪军 博士 Dr. Jijun Yuan

复宏汉霖首席科学官 CSO of Henlius

Henlius' R&D Strategic Plan

Major Modalities



Antibody: mAb, bispecific, multi-specific



ADC: single payload, multiple payloads



Fusion Protein: antibody fused with functional protein

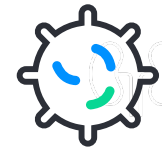


Small Molecule

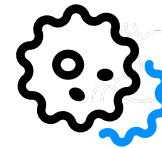
Key Indications



Tier1 Cancer: lung cancer, breast cancer, colon cancer



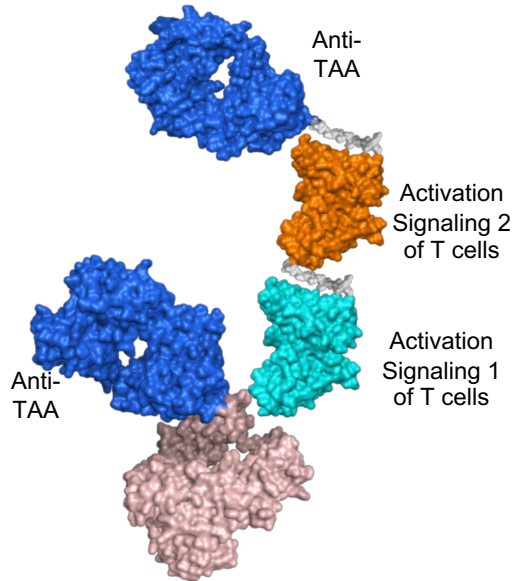
I&I Disease: IBD, SLE, atopic dermatitis, asthma, etc.



Tier2 Cancer: HCC, GC, PDAC, prostate cancer, etc.

Henlius' Technology Platforms

Tri-specific T cell engager



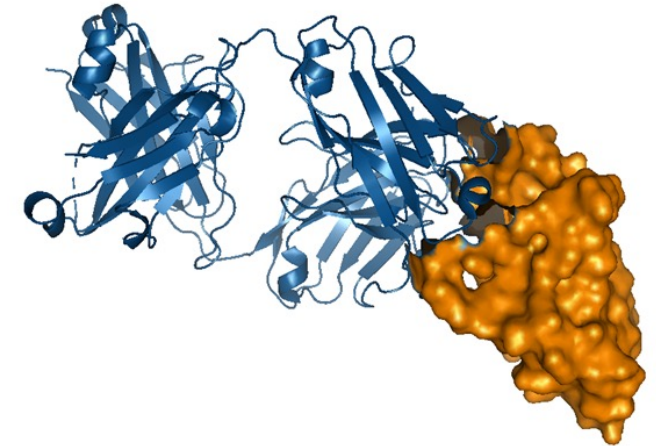
- Persistent specific T-cell activation effect
- Better efficacy in tumor microenvironment
- Reduced occurrence of CRS

Hanjugator™ ADC platform



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

HAI Club platform



- Targets identification & validation
- Cost reduction and efficiency improvement
- Increasing the success rate of drug discovery

Preclinical Pipeline Overview

PCC to IND stage:

	MOLECULE	INDICATION	Novelty
1	HLX37 PDL1xVEGF BsAb	Solid tumor	Fast Follow ●
2	HLX3901 DLL3xDLL3xCD3xCD28 TCE	SCLC	BIC ●
3	HLX316 B7H3-sialidase fusion protein	Solid tumor	FIC ●
4	HLX97 KAT6 A/B inhibitor	BC	BIC ●
5	HLX48 EGFRxcMet BsADC	NSCLC, CRC	BIC ●
6	HLX3902 STEAP1xSTEAP1xCD3xCD28 TCE	Prostate cancer	BIC ●
7	HLX41 LIV1 ADC	BC	BIC ●
8	HLX403	Solid tumor	BIC ●
9	HLX49	Solid tumor	BIC ●
10	HLX85	Solid tumor	FIC ●
11	HLX402	Solid tumor	FIC ●
12	HLX109	I&I disease	BIC ●

Discovery stage:

	MOLECULE	INDICATION	Novelty
1	HLX68	I&I disease	Fast Follow ●
2	HLX67	I&I disease	BIC ●
3	HLX105 antibody fusion protein	Solid tumor	BIC ●
4	HLX318 BAFFxTACIxBCMA fusion protein	I&I disease	BIC ●
5	HLX320	I&I disease	BIC ●
6	HLX69	CNS	Fast Follow ●
7	HLX321	Solid tumor	BIC ●
8	HLX322	Solid tumor	BIC ●
9	HLX323	Solid tumor	BIC ●
10	HLX86	Solid tumor	BIC ●
11	HLX203	Obesity	Fast Follow ●
12	HLX204	Obesity	FIC ●
13	HLX108	Solid tumor	FIC ●

Ratio of FIC/BIC/fast follow:
5 : 16 : 4

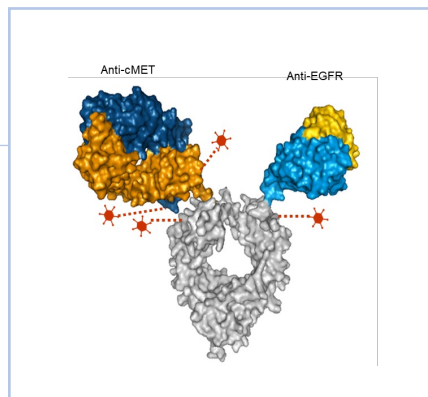
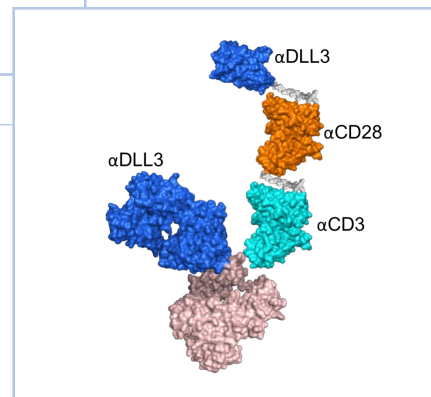
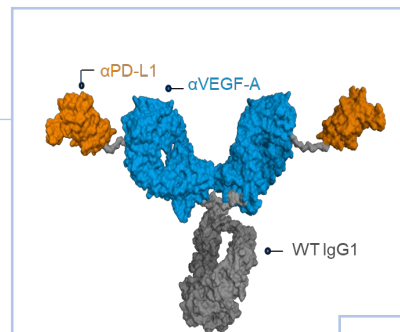
FIC

BIC

fast
follow

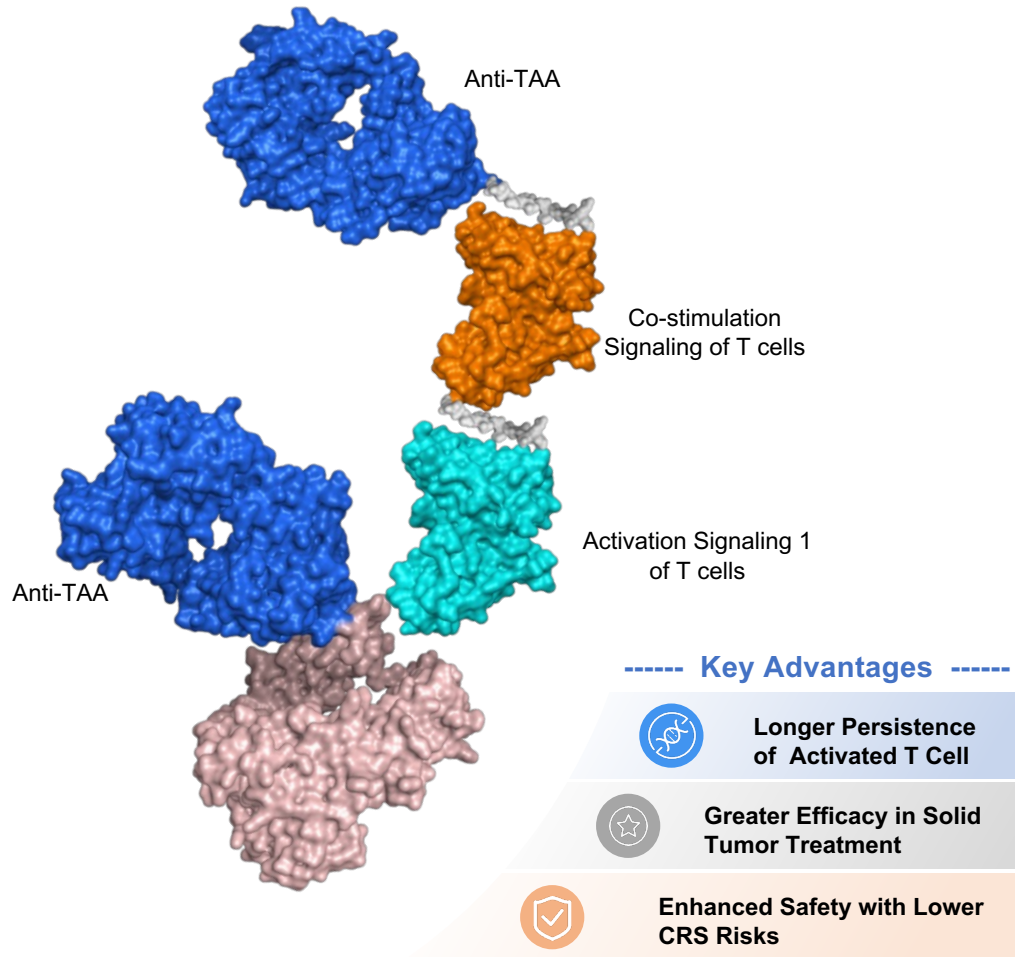
Preclinical Pipeline – Lung Cancer

MOLECULE	INDICATION
HLX37 PDL1xVEGF BsAb	Solid tumor
HLX3901 DLL3xDLL3xCD3xCD28 TCE	SCLC
HLX316 B7H3-sialidase fusion protein	Solid tumor
HLX97 KAT6 A/B inhibitor	BC
HLX48 EGFRxcMet BsADC	NSCLC, CRC
HLX3902 STEAP1xSTEAP1xCD3xCD28 TCE	Prostate cancer
HLX41 LIV1 ADC	BC
HLX403	Solid tumor
HLX49	Solid tumor
HLX85	Solid tumor
HLX402	Solid tumor
HLX109	I&I disease



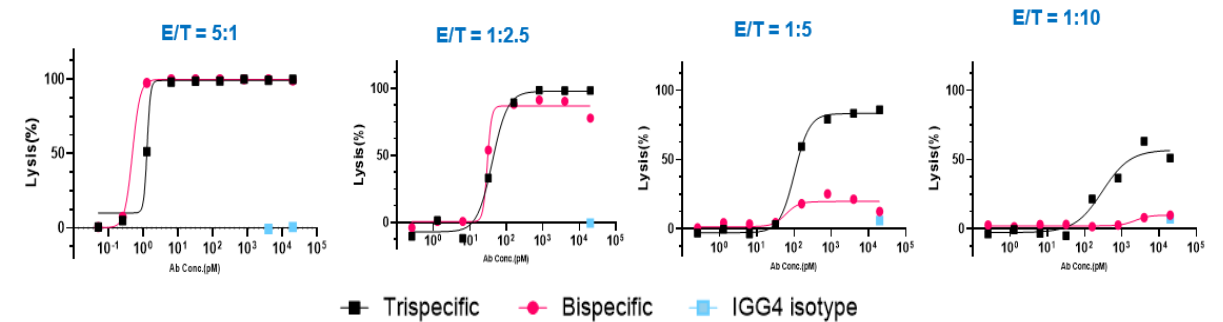
MOLECULE	INDICATION
HLX68	I&I disease
HLX67	I&I disease
HLX105 antibody fusion protein	Solid tumor
HLX318 BAFFxTACIxBCMA fusion protein	I&I disease
HLX320	I&I disease
HLX69	CNS
HLX321	Solid tumor
HLX322	Solid tumor
HLX323	Solid tumor
HLX86	Solid tumor
HLX203	Obesity
HLX204	Obesity
HLX108	Solid tumor

Henlius Advanced TAAxCD3xCD28 Multi-specific TCE Platform

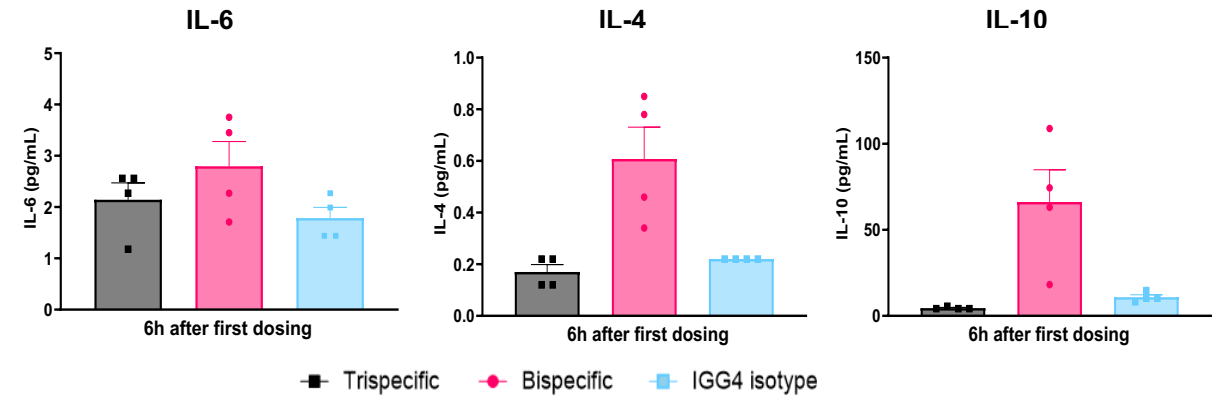


Efficacy: better in lower E/T ratio

Effector (PBMC)/Tumor ratios: from 5:1 to 1:10



Safety: Lower CRS



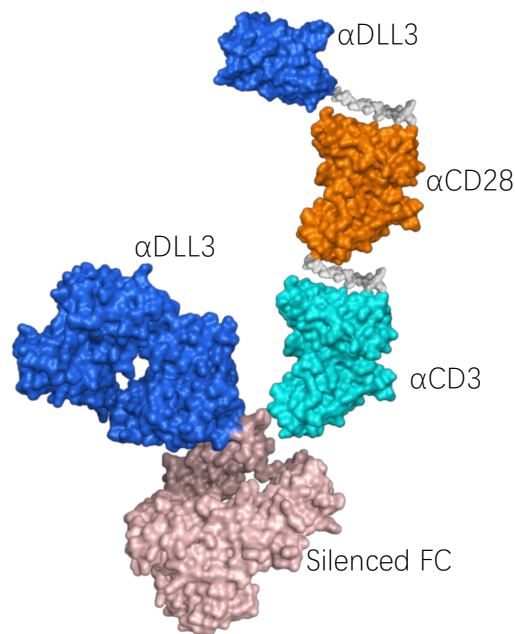
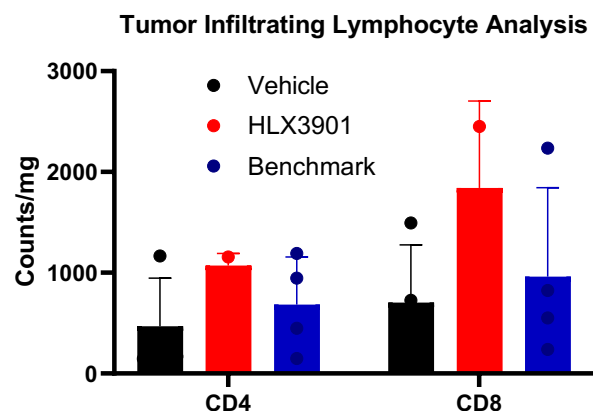
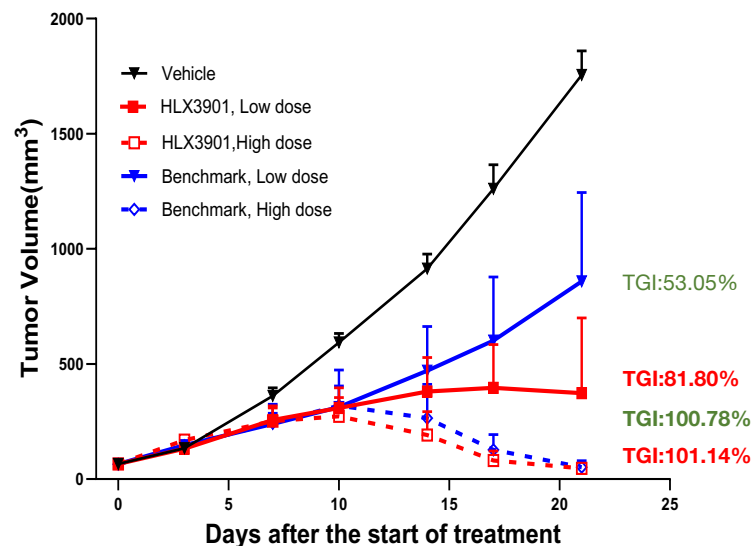
FORGING THE FUTURE

开创未来

国际肺癌前沿及创新论坛
INTERNATIONAL SUMMIT ON FRONTIERS AND INNOVATIONS IN LUNG CANCER

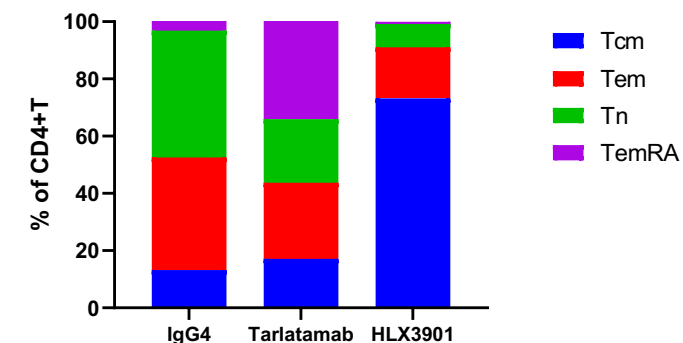
HLX3901: The “Best-in-Class” DLL3 TCE

HLX3901 is more efficacious than competitor compounds in the SHP-77 model

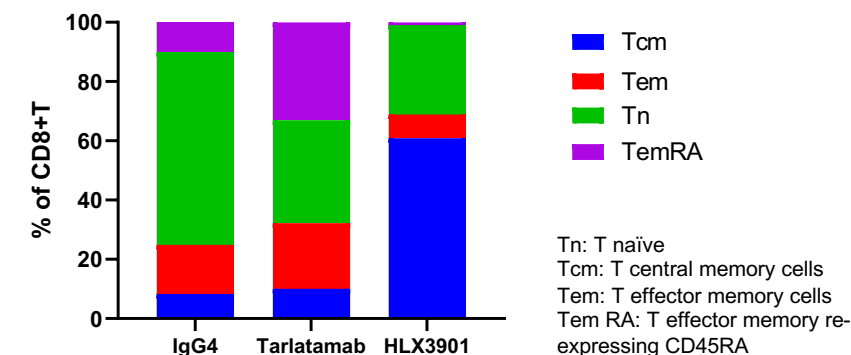


HLX3901 is More Effective in Inducing the Formation of Memory Cells

CD4+T cell memory subset expansion

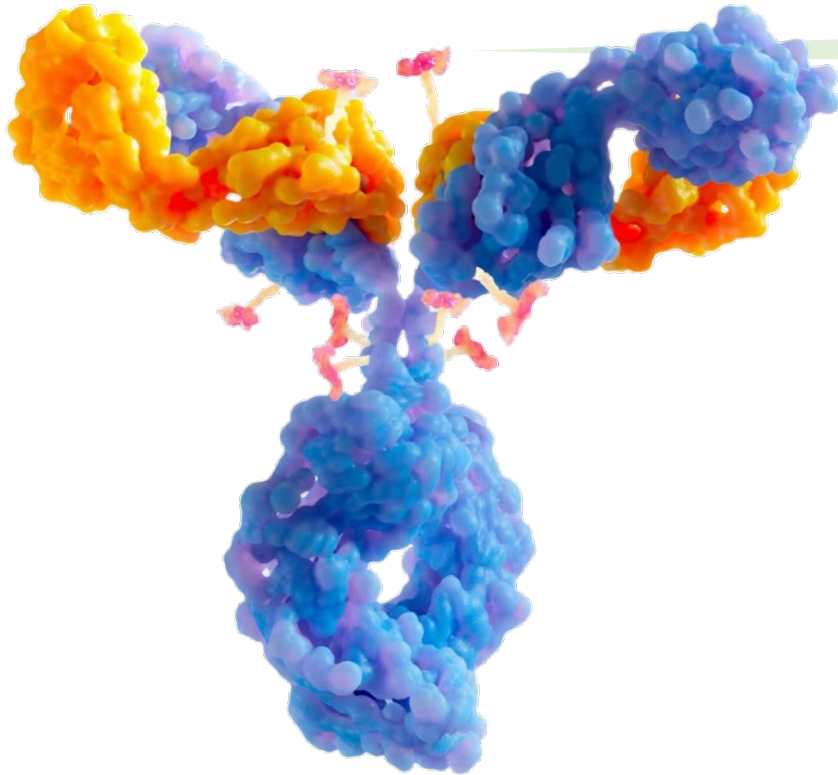


CD8+T cell memory subset expansion



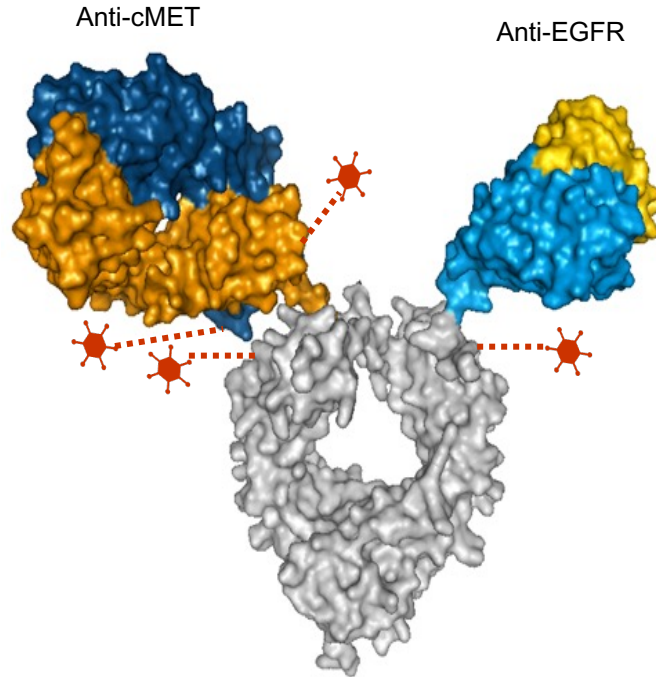
Tn: T naïve
Tcm: T central memory cells
Tem: T effector memory cells
Tem RA: T effector memory re-expressing CD45RA

Hanjugator ADC Platform with Enhanced Efficacy and Safety Profile



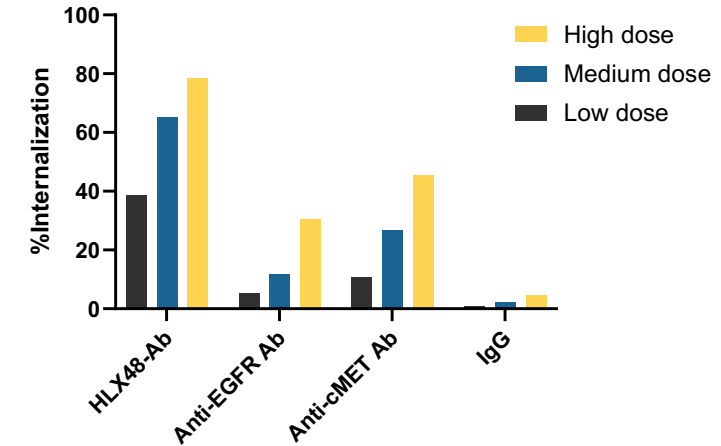
- Good safety profile, maximizes antibody function.
- Highly hydrophilic, compatible to various monoclonal and multi-specific antibodies.
- Excellent stability, minimal peripheral toxin release.
- Tenfold stronger bystander effect compared to Deruxtecan-conjugated ADCs, better efficacy, addresses tumor heterogeneity.

HLX48: Anti-EGFR X cMET ADC for NSCLC and CRC

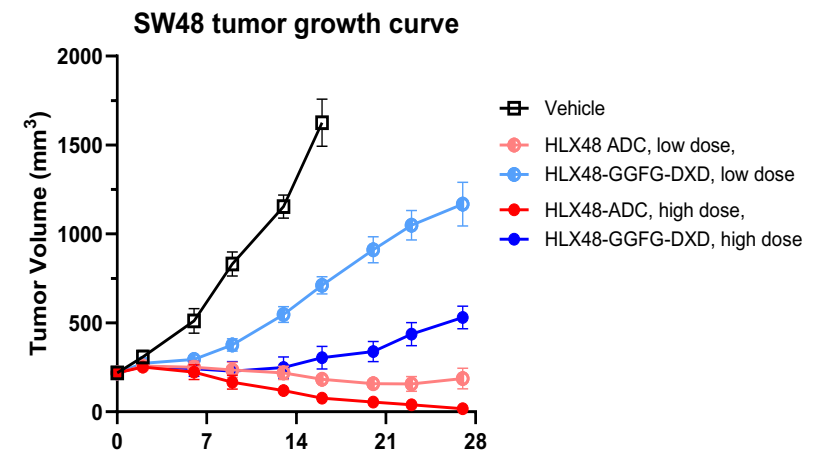


- A higher affinity for cMET and a lower affinity for EGFR is selected to mitigate toxicity
- Improved therapeutic window to maximize antibody function
- A stronger bystander effect, addressing the issue of tumor heterogeneity

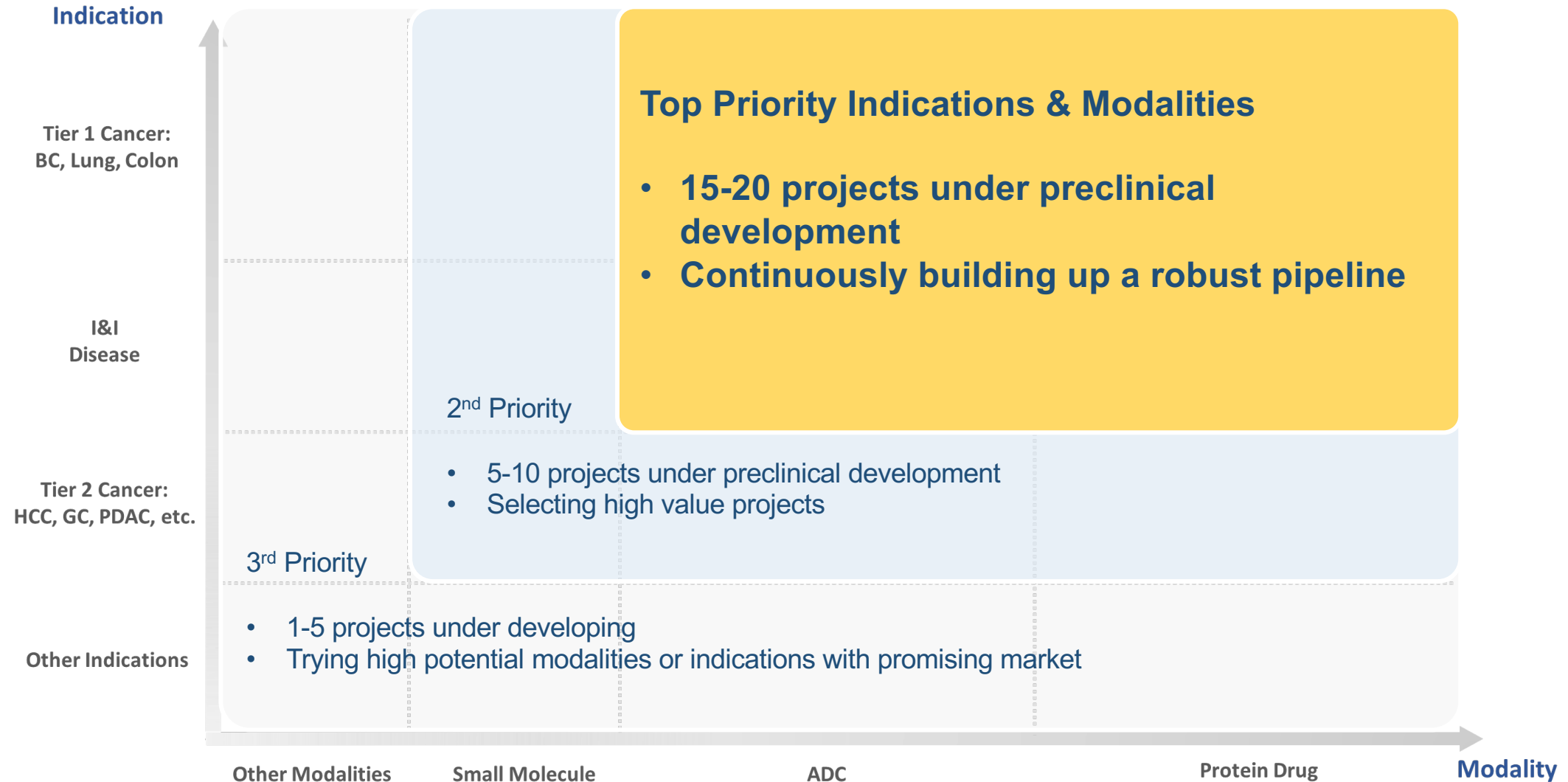
Bispecific Ab with higher internalization efficiency



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



Henlius R&D Landscape



The background features a dark blue gradient with dynamic, flowing light patterns in shades of blue and purple. These patterns resemble energy waves or smoke, creating a sense of movement and depth. The word "THANKS" is centered in a bold, white, sans-serif font.

THANKS