Henlius Biotech (2696.HK):
Serplulimab U.S. Bridging Study & 1L SCLC Strategy with PD-L1 ADC and DLL3 TCE

Dr. Qingyu Wang, MD

October 27th, 2026

以患者为中心 PATIENT CENTRICITY



Henlius Poised to Become a Global Leader in Lung Cancer Therapeutics

EGFR (AGA+)

1L
- HLX903 (3rd Gen EGFR TKI)+ HLX48 (c-MET x EGFR BsADC)

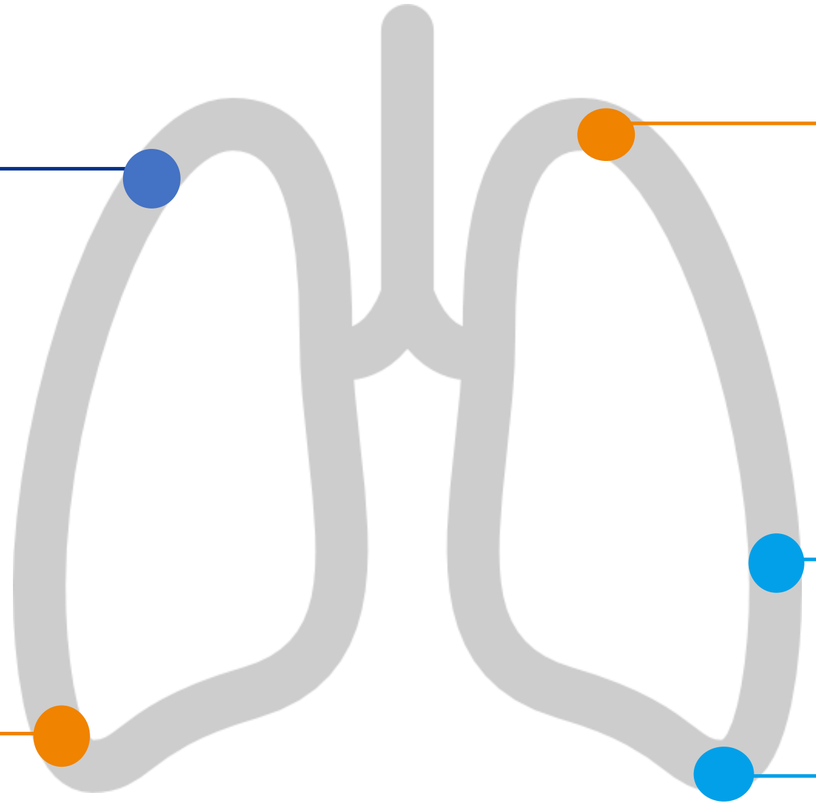
2L
- IO + HLX43 (PD-L1 ADC)
- HLX48 (c-MET x EGFR BsADC)

sqNSCLC (AGA-)

Peri-op
- IO + HLX43 (PD-L1 ADC) (1B-IIIA resectable)

1L
- Serplulimab+ chemo*
- Serplulimab+HLX07+chemo
- IO +HLX43 (PD-L1 ADC)
- HLX37 (PD-L1 x VEGF BsAb)+chemo

2L
- HLX43 (PD-L1 ADC)
- HLX105 (PD-1 x IL2v BsAb)



nsqNSCLC (AGA-)

Peri-op
- IO+HLX43 (PD-L1 ADC) (1B-IIIA resectable)

1L
- Serplulimab+ chemo*
- IO +HLX43 (PD-L1 ADC)
- HLX37 (PD-L1 x VEGF BsAb)+chemo

2L
- HLX43 (PD-L1 ADC)
- HLX105 (PD-1 x IL2v BsAb)

LS-SCLC

1L
- Serplulimab+ chemo/RT
- Serplulimab +HLX3901 (DLL3 x DLL3 x CD3 x CD28 TetraAb)
- HLX37 (PD-L1 x VEGF BsAb)+ chemo

ES-SCLC

1L
- Serplulimab+ chemo *
- Serplulimab +HLX3901 (DLL3 x DLL3 x CD3 x CD28 TetraAb)
- HLX37 (PD-L1 x VEGF BsAb)+ chemo

AGA+ EGFR 37w

AGA- sqNSCLC 24w | nsqNSCLC 25w

SCLC LS 5w | ES 11w

*Approved in 50 countries and regions, including China, the UK, Germany, India, Singapore. Approved indications may vary by country or region. Trade name: Hetronifly® in Europe. Business partners: KGBio / Fosun Pharma / Intas / Lotus / Abbott / Eisai

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Henlius Strategy in 1L SCLC

A full-disease-course approach, from limited-stage treatment to extensive-stage and next-generation pipelines

GLOBAL EPIDEMIOLOGY

≈268,000 cases

Estimated new SCLC cases worldwide, 2022

CHINA EPIDEMIOLOGY

≈150,000 cases

Estimated new SCLC cases in China, 2024

STAGE AT DIAGNOSIS

Limited-stage	Extensive-stage
25%–35%	65%–75%

LIMITED-STAGE SCLC

A. Epidemiology & clinical context

- ≈25%–35% of patients present with limited-stage disease
- Backbone: platinum–etoposide plus concurrent thoracic radiotherapy
- Goal: durable disease control and long-term survival benefit

B. Henlius treatment strategy

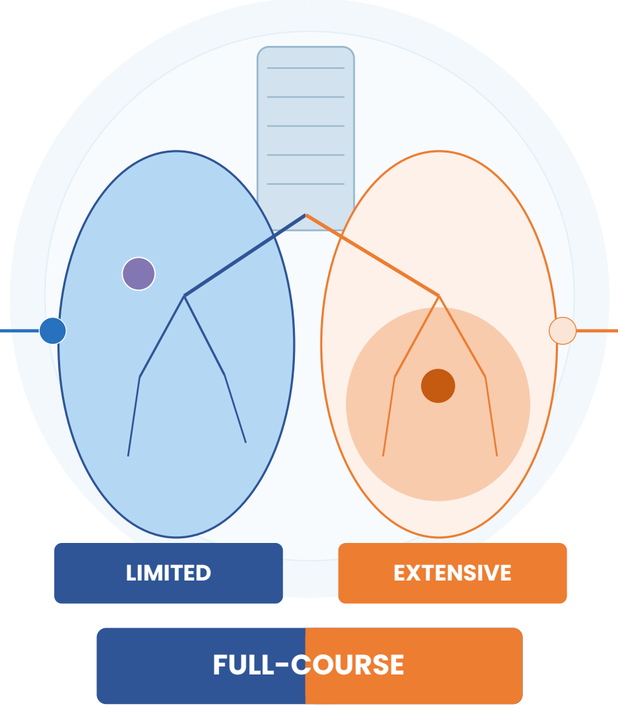
Serplulimab (HLX10)

HLX10-020-SCLC | Phase III, ongoing

Serplulimab + chemotherapy + concurrent radiotherapy

Investigational regimen in limited-stage SCLC

FULL DISEASE-COURSE COVERAGE



EXTENSIVE-STAGE SCLC

A. Epidemiology & clinical context

- ≈65%–75% present with extensive-stage disease
- Rapid progression and frequent relapse create unmet later-line needs
- 1L treatment commonly combines immunotherapy with chemotherapy

B. Henlius strategy: approved 1L

Serplulimab (HLX10) + chemo

Phase III: ASTRUM-005 (HLX10-005-SCLC)

Approved first-line treatment in Europe, China and multiple other countries, bridging in US and JP

C. Later-line / pipeline development

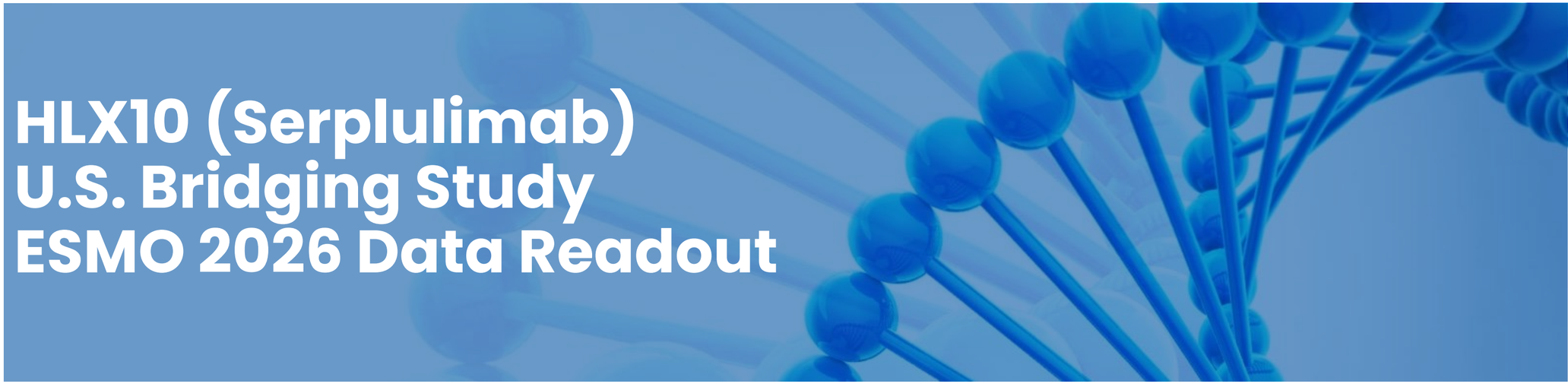
HLX3901	HLX37
T-cell engager	PD-L1/VEGF BsAb

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01

HLX10 (Serplulimab) U.S. Bridging Study ESMO 2026 Data Readout



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MADRID 2026 ESMO congress

Randomized trial of serplulimab or atezolizumab plus chemotherapy in USA patients with extensive-stage small cell lung cancer (ASTRIDE)

David R. Gandara[1], Evan Wu[2], Eric Schaefer[3], Rama Balaraman[4], Faris Badin[5], Murtaza Bhuriwala[6], Vu Phan[7], Mitchell Haut[8], Nagaprasad Nagajothi[9], Sumit Sawhney[10], Omar Abughanimeh[11], Shaker Dakhil[12], Santosh Nair[13], Roger S. Keresztes[14], Nikki James[15], Hongyan Ni[15], Qingyu Wang[15], Afshin Dowlati[16]

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ESMO

Background

- The global phase 3 ASTRUM-005 trial demonstrated survival benefits with serplulimab-chemotherapy for treatment-naïve extensive-stage small cell lung cancer (ES-SCLC)[1].
- Confirmatory data for consistency of ASTRUM-005 findings in USA patients was required.
- Moreover, there is no prospective data directly comparing different immune checkpoint inhibitors in this setting.

Here we present the randomised ASTRIDE bridging trial, comparing serplulimab-chemotherapy versus atezolizumab-chemotherapy in USA patients with ES-SCLC.

USA, United States of America.

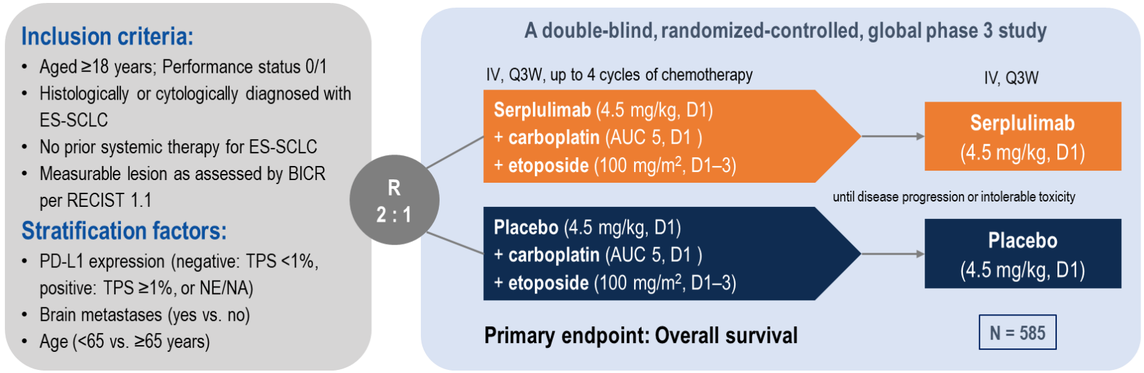
1. JAMA. 2022 Sep 27;328(12):1223-1232.

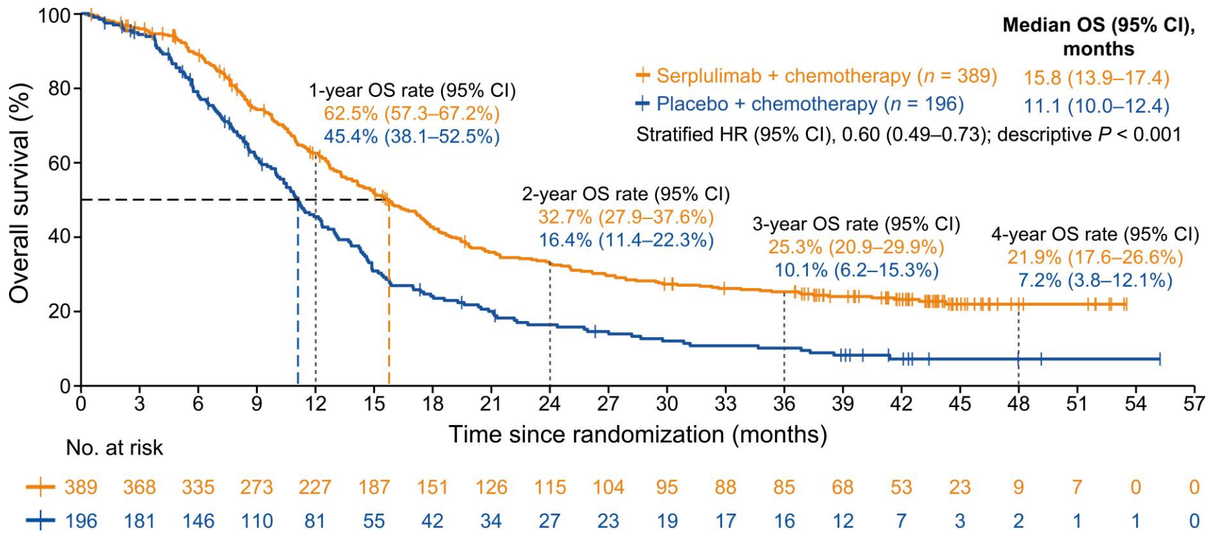
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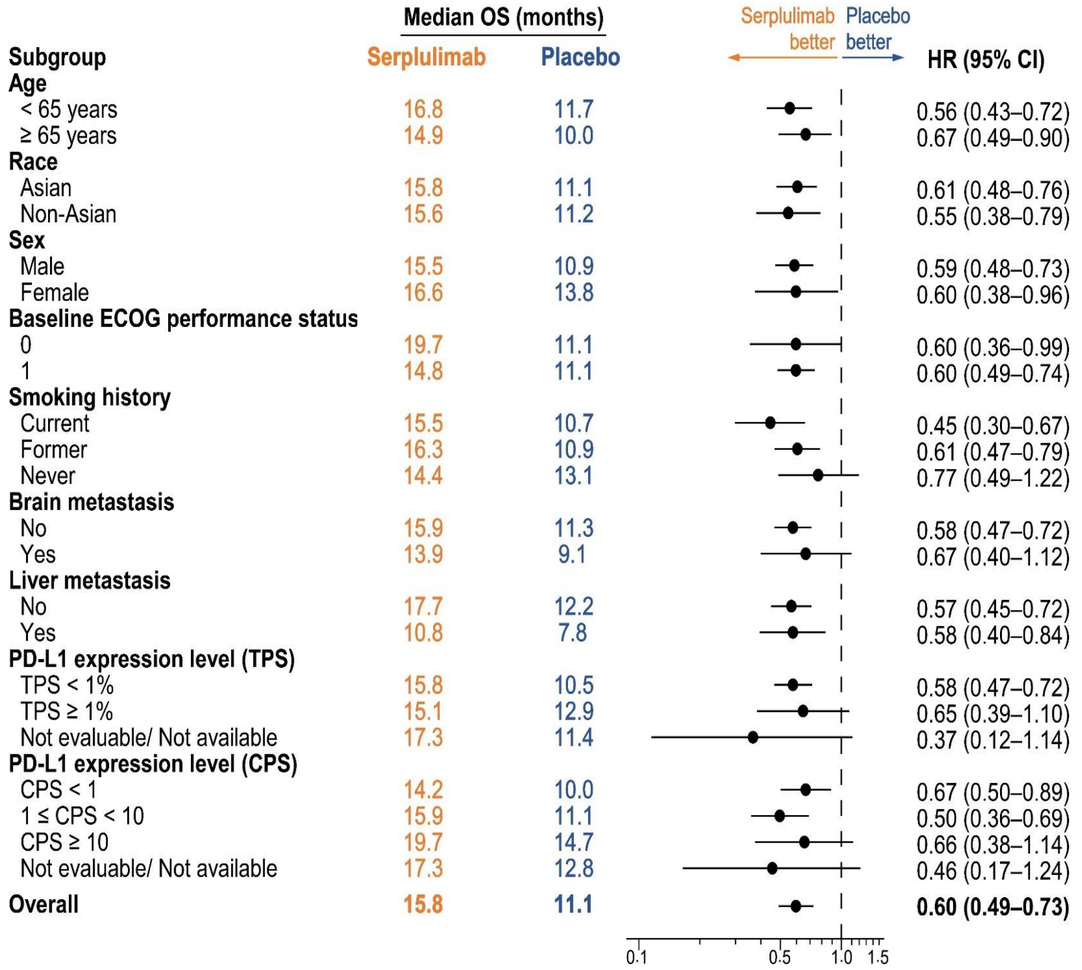
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Background: ASTRUM-005: Serplulimab ± carboplatin-etoposide in ES-SCLC[1,2]

Patients were screened across six countries: China, Ukraine, Poland, etc. Of these, 401 were Asian and 184 were non-Asian.







1. Ying Cheng et al. J Clin Oncol 43, 8093-8093(2025); 2. Liu J, Han L, Wu L, et al. JAMA Oncol. 2026;12(8):810–818.

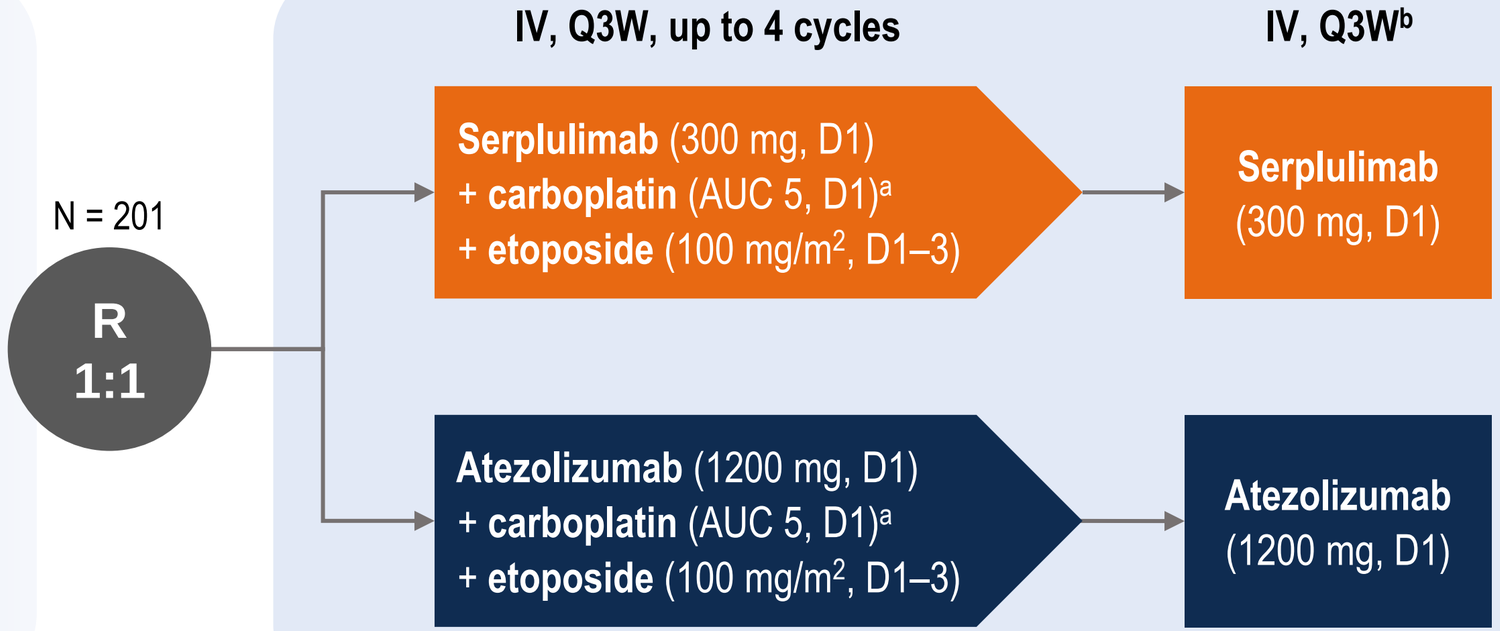
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ASTRIDE study design

Between 2022 and 2025, a total of 201 patients were enrolled at 70 study sites across the United States.

Key eligibility criteria:

- Age ≥18 years;
- Performance status 0/1;
- Histologically or cytologically confirmed ES-SCLC;
- No prior systemic therapy for ES-SCLC (Patients who have received one cycle of chemotherapy for newly diagnosed ES-SCLC are eligible);
- Measurable disease as assessed by BICR per RECIST v1.1.



Descriptive Statistical Analysis: Primary endpoint: Overall survival

Secondary endpoints: PFS, ORR, DOR, safety, pharmacokinetics, immunogenicity, quality of life, exploratory biomarker analysis.

[a] Up to 750 mg. [b] Until disease progression, intolerable toxicity, discontinuation decided by the participant or the investigator, death, withdrawal of informed consent, pregnancy, noncompliance with protocol or procedure requirements, administrative reasons, or other protocol-specified reasons, whichever occurred first.

AUC, area under the curve; BICR, blinded independent central review; D, day; DOR, duration of response; ES-SCLC, extensive-stage small-cell lung cancer; IV, intravenous; ORR, objective response rate; PFS, progression-free survival; Q3W, every 3 weeks; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors.

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Descriptive statistical design

Design principles

- Randomized, head-to-head, descriptive bridging study in USA patients.
- Objective: regulatory bridging; assess trends between groups and supplement US efficacy, safety, and PK data.
- No formal hypothesis.
- All HRs, ORs, and CIs are descriptive effect estimates with uncertainty.

Endpoints and statistical methods

- **OS (primary endpoint):**
  - Median OS and 95% CI will be estimated using the Kaplan–Meier method.
  - HR and 95% CI will be estimated using a Cox proportional hazards model.
- **PFS (secondary endpoint)** — assessed by BICR and investigator per RECIST 1.1:
  - Cox proportional hazards model for HR and 95% CI; Kaplan–Meier method for median and 95% CI.
- **ORR (secondary endpoint)** — assessed by BICR and investigator per RECIST 1.1:
  - ORR by group and corresponding 95% exact CI will be calculated using the Clopper–Pearson method.
  - ORR odds ratio and 95% CI will be estimated.

Analysis timing

Interim analysis

- When the ORR data of approximately 200 patients have been collected for 18 weeks.

Final OS analysis

- 12 months after the last patient is enrolled.

BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; OR, odds ratio; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; RECIST, Response Evaluation Criteria in Solid Tumors; US, United States;.

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ASTRIDE amendment (June 2024): 1st cycle chemotherapy

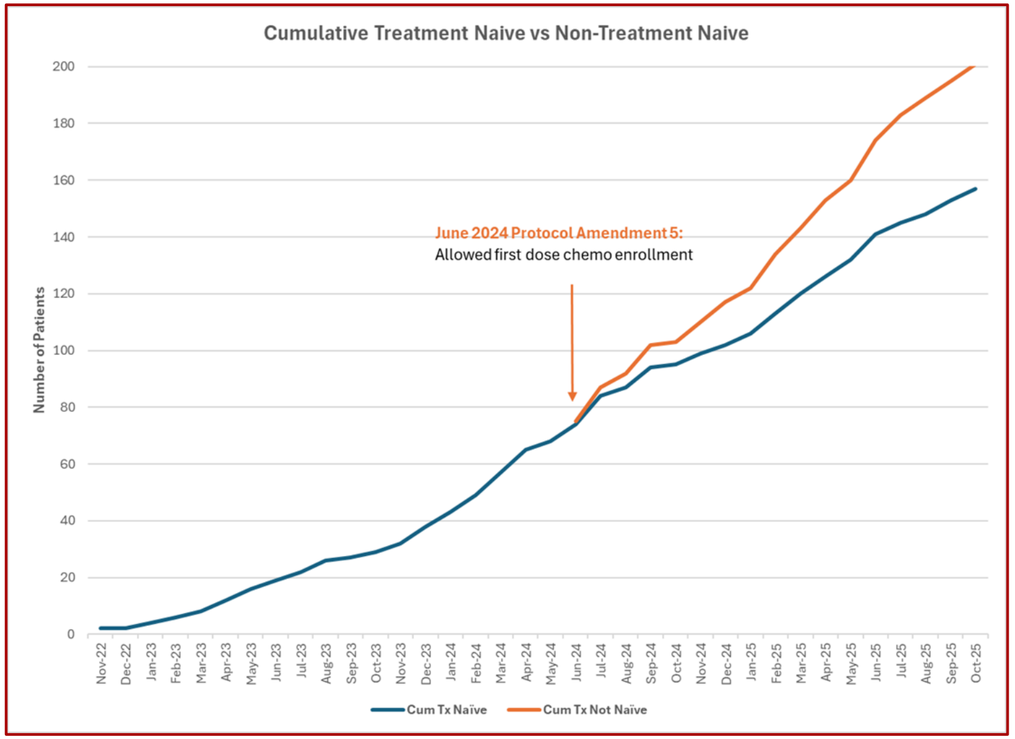
Rationale: Align to U.S. practice for newly diagnosed ES-SCLC patients

Key Change:

- **Permits first cycle of chemotherapy prior to randomization**

  → Aligns with real-world U.S. hospital practice where initial chemotherapy cycle often starts before trial enrollment

- Amendment increased accrual



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Baseline characteristics and subsequent cancer therapy

Data cutoff date: February 18, 2026; **Median follow-up duration:** 14.1 months

ITT population: 201 patients; **Safety set:** 199 patients

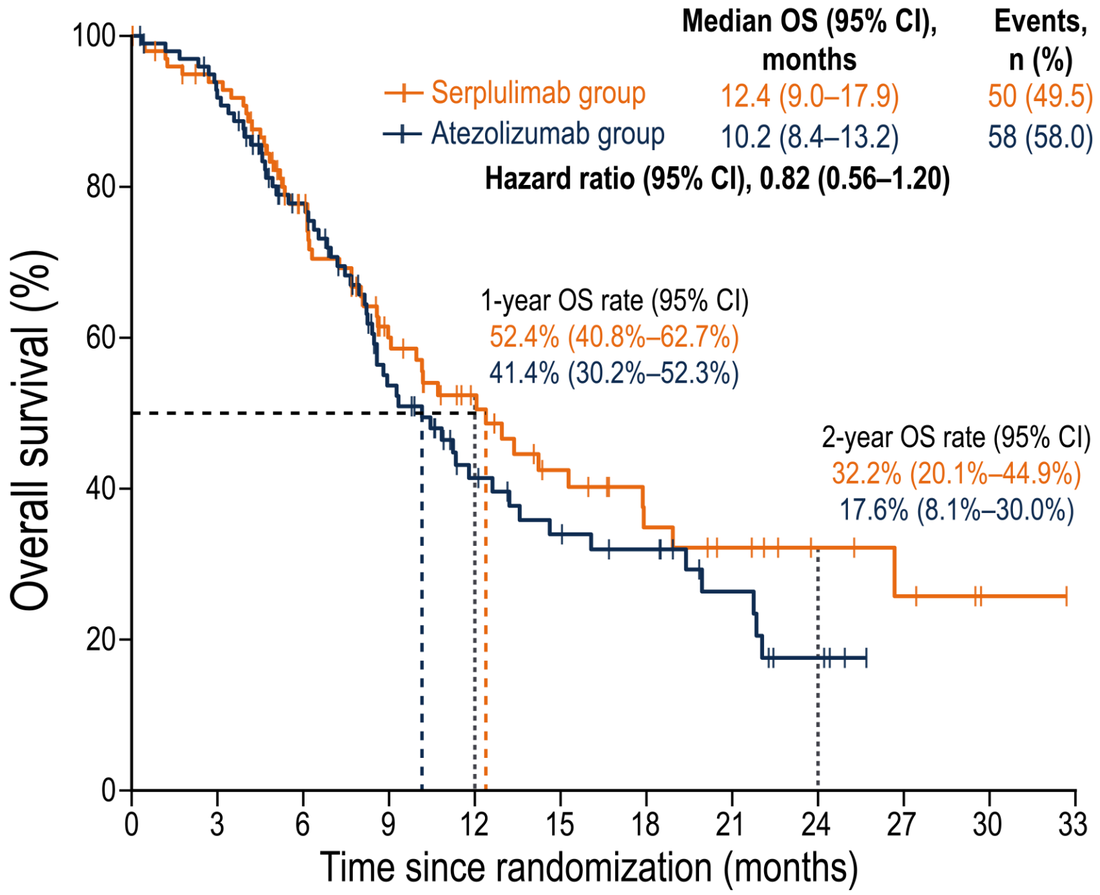
	Serplulimab (n = 101)	Atezolizumab (n = 100)
Age, median (range), years	68 (35–91)	67 (40–82)
<65 years, n (%)	39 (38.6)	37 (37.0)
≥65 years, n (%)	62 (61.4)	63 (63.0)
Sex, n (%)		
Female	55 (54.5)	47 (47.0)
Male	46 (45.5)	53 (53.0)
Performance status, n (%)		
0	30 (29.7)	23 (23.0)
1	70 (69.3)	76 (76.0)
≥2[a]	1 (1.0)	1 (1.0)
Race, n (%)		
American Indian or Alaska native	3 (3.0)	0
Asian	2 (2.0)	4 (4.0)
Black or African American	2 (2.0)	8 (8.0)
White	94 (93.1)	88 (88.0)
Sum of longest diameter of target lesions, median (range), mm	109.0 (12.0–262.0)	108.0 (17.0–273.0)
Smoking history, n (%)		
Current	35 (34.7)	28 (28.0)
Former	62 (61.4)	69 (69.0)
Never	4 (4.0)	3 (3.0)
Metastatic disease, n (%)	98 (97.0)	98 (98.0)
Liver metastasis	50 (49.5)	40 (40.0)
Bone metastasis	25 (24.8)	28 (28.0)
Brain metastasis	15 (14.9)	14 (14.0)
Had 1st cycle of chemotherapy, n (%)	19 (18.8)	24 (24.0)
Subsequent cancer therapy, n (%)	38 (37.6)	45 (45.0)
Chemotherapy	27 (26.7)	24 (24.0)
Lurbinectedin	22 (21.8)	16 (16.0)
Immunotherapy	16 (15.8)	20 (20.0)
Tarlatamab	13 (12.9)	15 (15.0)
Radiotherapy	21 (20.8)	21 (21.0)
Targeted therapy	1 (1.0)	1 (1.0)

[a] The most recent performance status evaluations prior to the first dose of study treatment are presented. One patient in each group had performance status 1 at screening and 2 before the first dose of study treatment.
ES-SCLC, extensive-stage small cell lung cancer.

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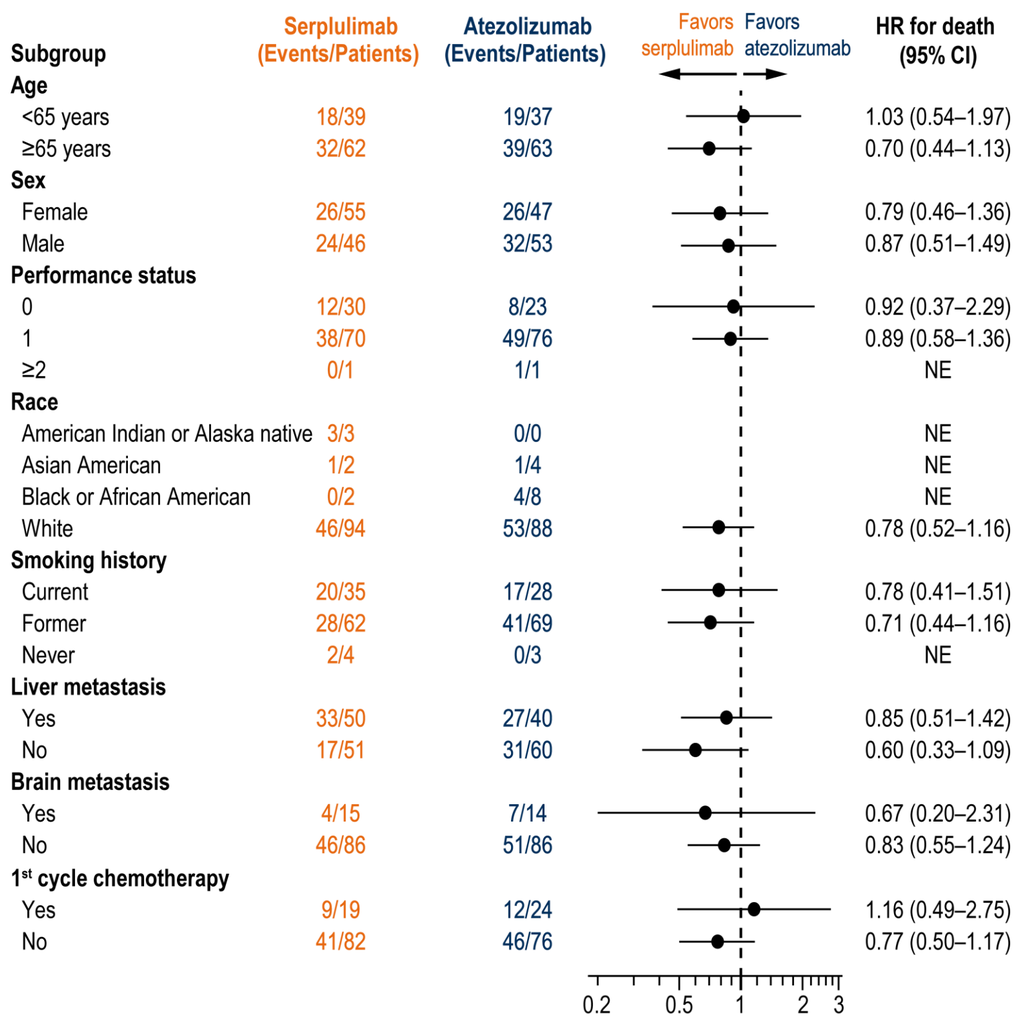
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Efficacy: OS and subgroup analysis



No. at risk (No. censored)

Serplulimab	101 (0)	90 (5)	66 (14)	41 (25)	28 (33)	19 (37)	13 (40)	10 (42)	6 (46)	4 (47)	1 (50)	0 (51)
Atezolizumab	100 (0)	89 (3)	67 (12)	39 (21)	24 (28)	18 (30)	15 (32)	9 (36)	4 (38)	0 (42)	0 (42)	0 (42)



CI, confidence interval; HR, hazard ratio; NE, not evaluable; No., number; OS, overall survival.

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Efficacy: Secondary endpoints assessed by BICR

	Serplulimab (n = 99)[a]	Atezolizumab (n = 100)
PFS[b], median (95% CI), months	5.4 (4.5–5.8)	4.9 (4.2–5.6)
HR (95% CI)	0.95 (0.67–1.35)	
Best overall response[c], n (%)		
Complete response	1 (1.0)	1 (1.0)
Partial response	64 (64.6)	66 (66.0)
Stable disease	25 (25.3)	21 (21.0)
Progressive disease	3 (3.0)	6 (6.0)
Not evaluable[d]	6 (6.1)	6 (6.0)
ORR[c] (95% CI), %	65.7 (55.4–74.9)	67.0 (56.9–76.1)
DOR[c], median (95% CI), months	4.2 (4.1–5.6)	4.0 (3.1–4.5)
HR (95% CI)	0.95 (0.62–1.47)	

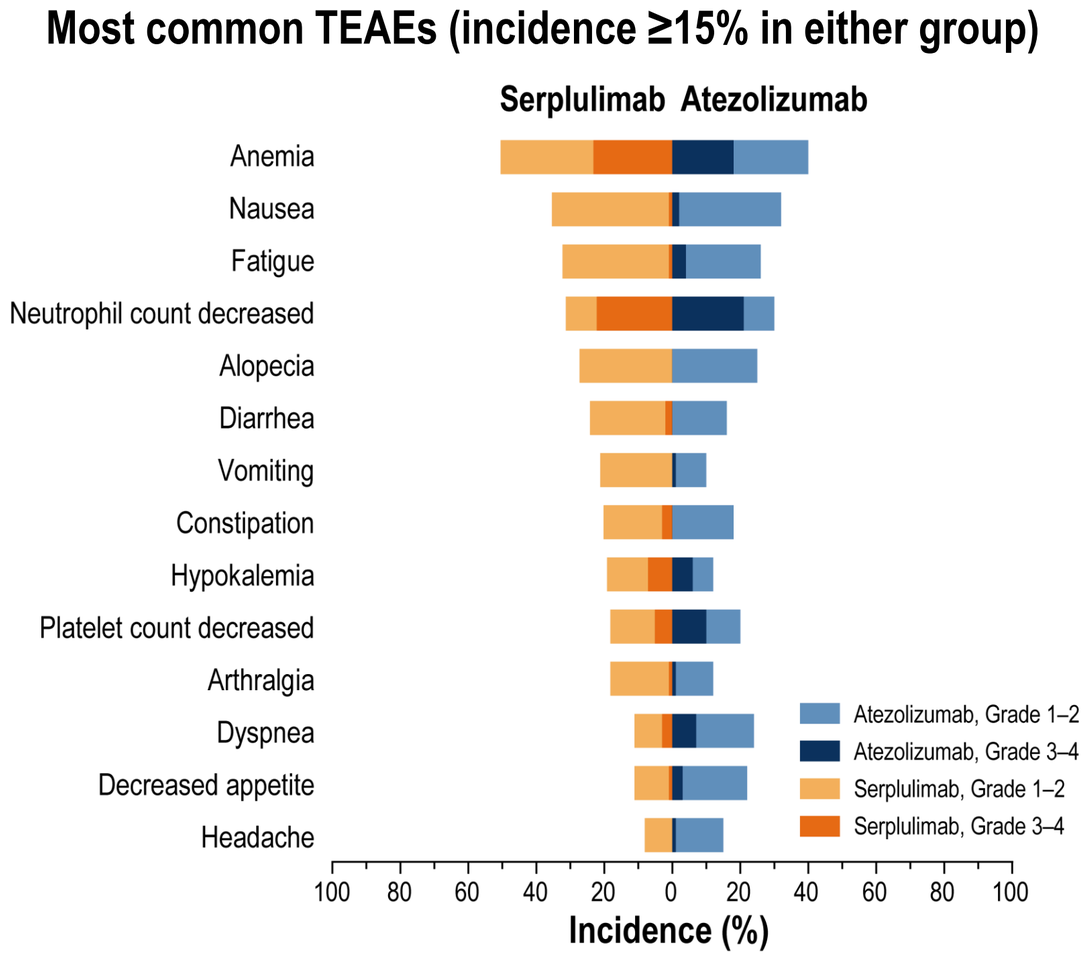
[a] Patients who did not receive study treatment were excluded from the secondary endpoint analyses. [b] According to BICR assessments per RECIST v1.1. [c] Based on confirmed tumor responses according to BICR assessments per RECIST v1.1. [d] These patients did not have post-treatment tumor assessment, except for one patient in the atezolizumab group with a non-evaluable target lesion at post-treatment tumor assessment.
BICR, blinded independent central review; CI, confidence interval; DOR, duration of response;; HR, hazard ratio; ORR, objective response rate; PFS, progression-free survival.

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Safety and tolerability

	Serplulimab (n = 99)	Atezolizumab (n = 100)
TEAE	97 (98.0)	99 (99.0)
Grade ≥3	73 (73.7)	73 (73.0)
Serious	44 (44.4)	46 (46.0)
Leading to Tx interruption	54 (54.5)	51 (51.0)
Leading to Tx discontinuation	16 (16.2)	12 (12.0)
Leading to death	9 (9.1)	8 (8.0)
TEAEs related to serplulimab or atezolizumab	63 (63.6)	68 (68.0)
Grade ≥3	20 (20.2)	25 (25.0)
Serious	9 (9.1)	7 (7.0)
Leading to Tx interruption	22 (22.2)	22 (22.0)
Leading to Tx discontinuation	5 (5.1)	4 (4.0)
Leading to death[a]	2 (2.0)	2 (2.0)
Adverse event of special interest	23 (23.2)	23 (23.0)
Infusion-related reaction	4 (4.0)	3 (3.0)
Immune-related adverse event	21 (21.2)	23 (23.0)



[a] One patient in the serplulimab had respiratory failure and septic shock, and the other one had respiratory failure. One patient in the atezolizumab group had colitis and septic shock, and the other one had myocarditis.
TEAE, treatment-emergent adverse event; Tx, treatment.

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Conclusions

- In the ASTRIDE trial, compared with atezolizumab, serplulimab was associated with
  - ➢ numerically longer median OS
    - ✓ ITT population: 12.4 versus 10.2 months, HR 0.82; 95% CI, 0.56–1.20
    - ✓ No 1st cycle chemotherapy: 13.4 versus 10.8 months, HR 0.77; 95% CI, 0.50–1.17
  - ➢ similar PFS, ORR, DOR outcomes
  - ➢ similar safety profiles

Serplulimab-chemotherapy compared favorably with atezolizumab-chemotherapy, supporting the benefit of serplulimab and applicability of the ASTRUM-005 findings to the USA patients with treatment-naïve ES-SCLC.

CI, confidence interval. DOR, duration of response; ES-SCLC, extensive-stage small cell lung cancer; HR, hazard ratio; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.

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02

HLX43 (PD-L1 ADC)

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

HLX43 (PD-L1 ADC)



1500+ patients with solid tumors enrolled

100+ US patients

>50% patients with NSCLC

*As of August 2026

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

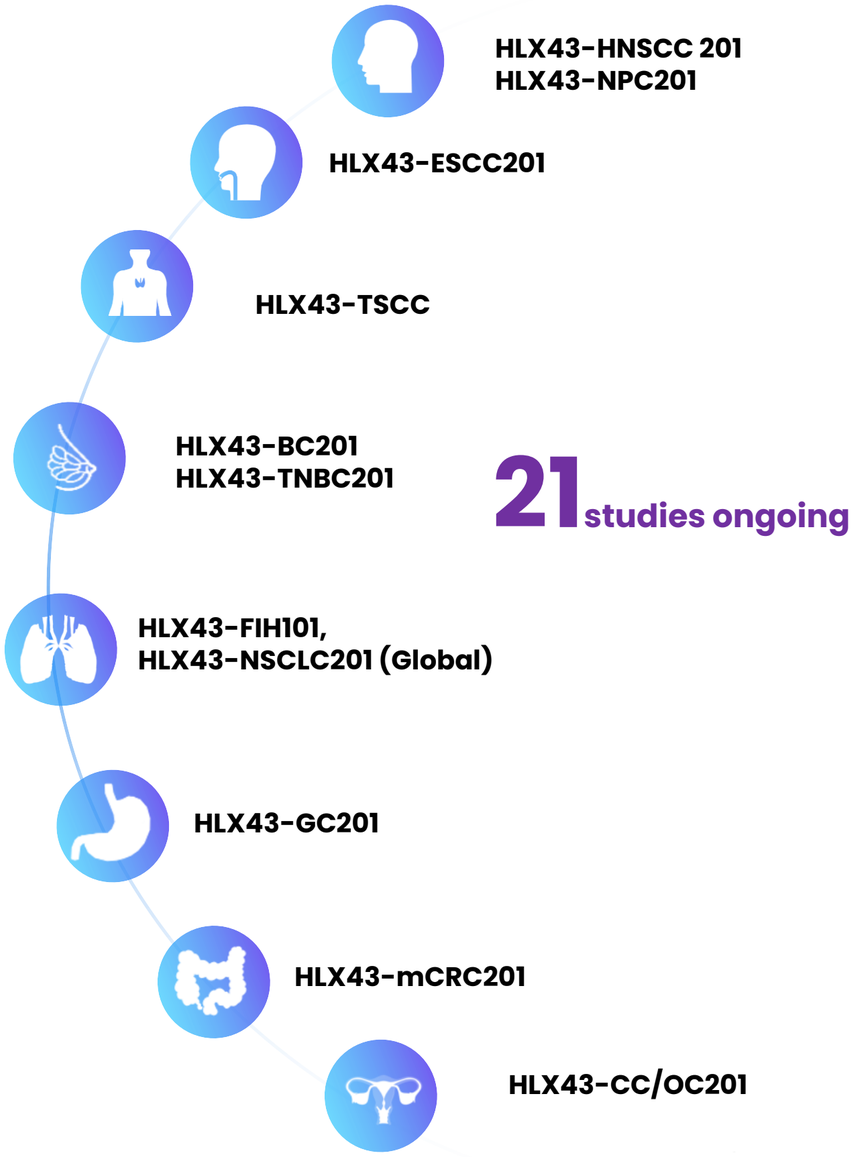
HLX43-NSCLC201: PD-L1 ADC Phase 2 Trial in Later-Line NSCLC

- MRCT led by top global KOLs
- Primary endpoint: ORR (IRRC)
- Countries and regions involved: CN, US, EU, AUS, and JP
- Key milestone: As of Aug 19, 2026, a total of 236 patients had been enrolled globally, with 147 patients ex-China (96 from US, 18 from AUS, 13 from JP, and 20 from EU).

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HLX43 (PD-L1 ADC): Broad Potential Across Tumor Types

	Incident Cases (k)	LoT	Regimen	Clinical Stage	Released Data
NSCLC	1,411	AA nsqNSCLC ≥2L	HLX43 Mono	Pivotal Planned	cORR 36.8%, PFS 6.67m
		Non-AGA 1L	HLX43±HLX10	Ph2	-
		sqNSCLC 2L	HLX43±HLX07	Ph2/3	
		sqNSCLC ≥2L	HLX43 Mono	Ph2	cORR 46.7%, PFS 6.90m
SCLC	250	1L ≥2L	HLX43±HLX10 HLX43 Mono	Ph2	-
AA TSCC	6	≥2L	HLX43 Mono	Ph2	cORR 58.3%, DCR 100%
mCRC	1,081	2L	HLX43+HLX04±Chemo HLX43+HLX07 HLX43+HLX10	Ph2	-
GC	559	≥2L	HLX43 Mono	Ph2	cORR 50%, DCR 90%
AA ESCC	239	≥2L	HLX43 Mono	Ph2	ORR 61.5%, DCR 100%
HR+BC	710	≥2L	HLX43 Mono	Ph2	-
TNBC	140	1L	CPS<10: HLX43 Mono CPS≥10: HLX43+HLX10	Ph2	-
		2L	HLX43 Mono	Ph2	-
HNSCC	225	1L	HLX43+HLX10±HLX07	Ph2	-
NPC	56	≥3L	HLX43 Mono	Ph2	ORR 70%, DCR 80%
CC	191	≥2L	HLX43 Mono	Ph2	ORR 70%, DCR 100%
OC	122	Platinum-resistant	HLX43 Mono	Ph2	



AA Seeking accelerated approval in China and the US

*Annual new cases in the US, five major EU countries, China, and Japan, estimated using GLOBOCAN 2022 data and external literature.

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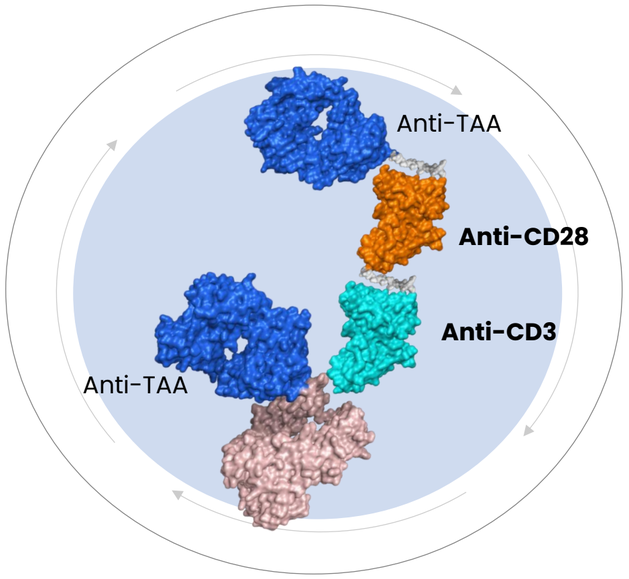
03

HLX3901 (DLL3 x DLL3 x CD3 x CD28 tetra-specific TCE)

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Immune Cell Engager Platform: Two Innovative Assets in Phase 1

Tri-TCE



Durable, specific T-cell activation.

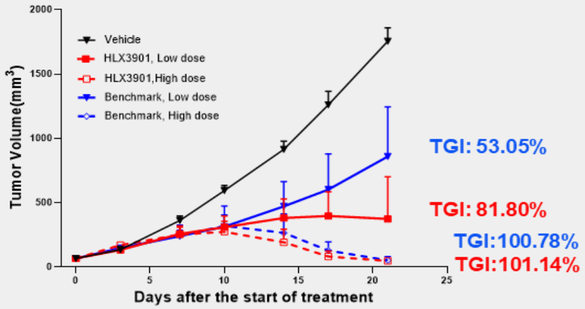
Enhanced efficacy in low immune-infiltrated tumor microenvironments

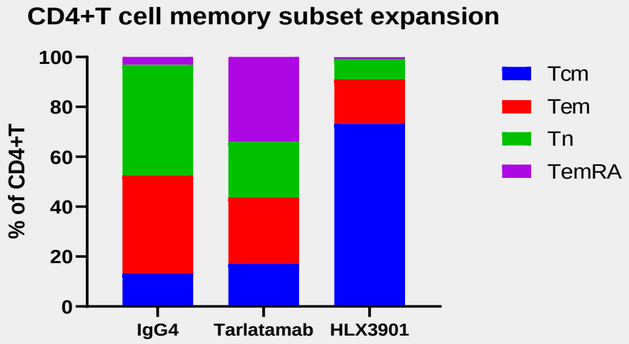
Low cytokine release and wide safety window.

Key Pipelines from Tri-TCE Platform:

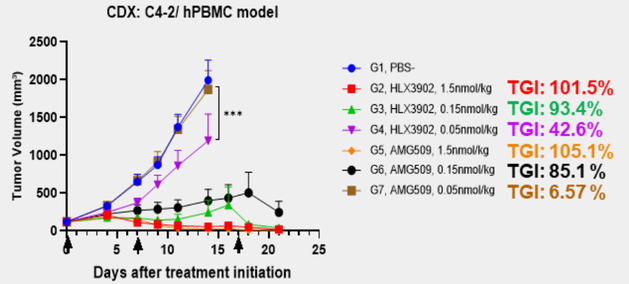
- **HLX3901 (DLL3×DLL3×CD3×CD28, tetra-specific TCE) - Ph1**
- **HLX3902 (STEAP1×CD3×CD28, TCE) - Ph1**

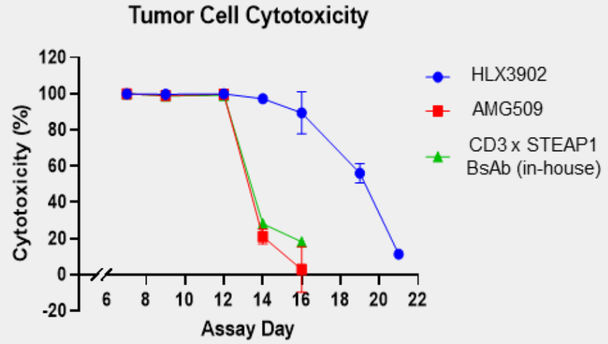
HLX3901 Superior anti-tumor activity Enhanced Tcm induction





HLX3902 Stronger anti-tumor activity More durable tumor cell killing





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

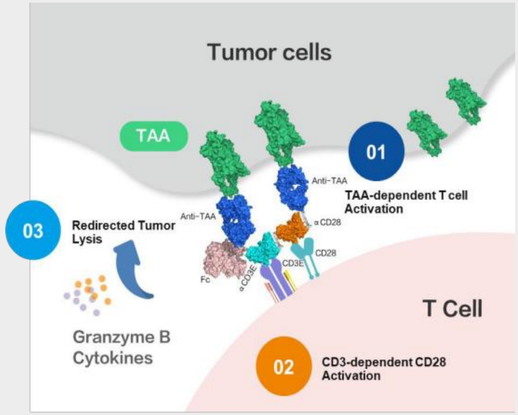
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HLX3901: A BIC DLL3xDLL3xCD3xCD28 Tetra-specific TCE for the Treatment of SCLC

2026 IND

HLX3901 (DLL3xDLL3xCD3xCD28) MOA

- DLL3 biparatopic design enhances targeting specificity
- 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, addressing the problem of CD28 toxicity through the design of special epitopes and cis-binding design in TCE.



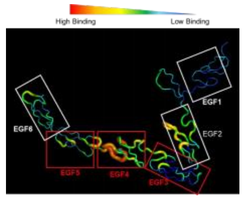
TAA: Tumor associated antigen

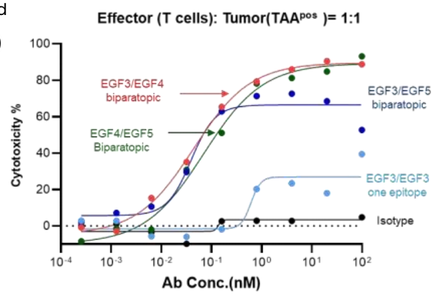
Key Strength:

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

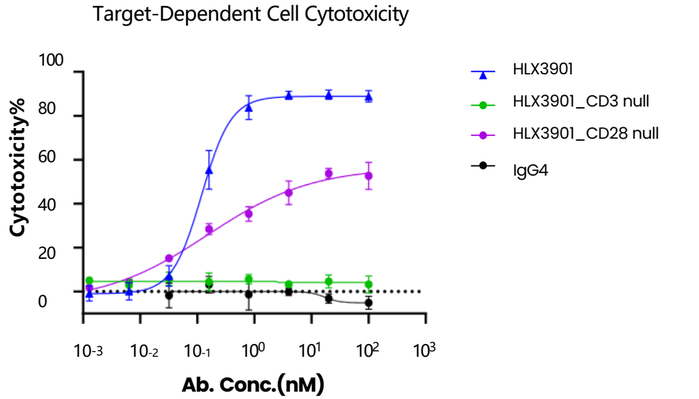
EGF3/EGF4 dual-epitope antibody significantly enhances the killing effect against DLL3-positive tumor cells

DLL3 bispecific epitope designed by AI (with EGF3/4/5 as the optimal antibody binding sites)

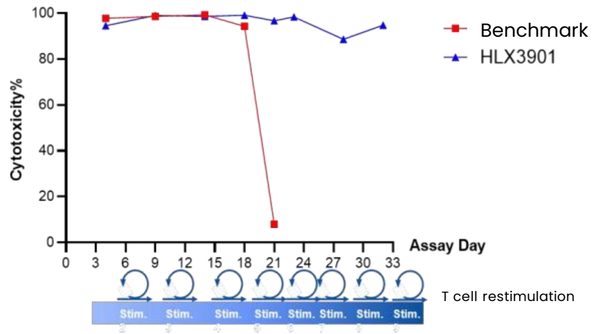




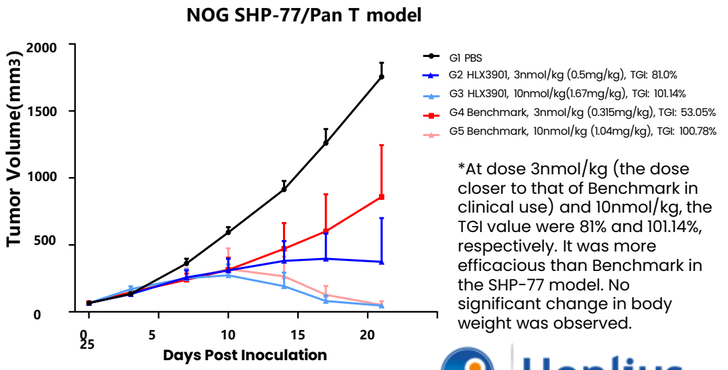
Effective activation of CD28 require co-engagement of CD3



HLX3901 exhibited sustained cytotoxicity activity



HLX3901 demonstrated superior antitumor activity compared to the competitors



*At dose 3nmol/kg (the dose closer to that of Benchmark in clinical use) and 10nmol/kg, the TGI value were 81% and 101.14%, respectively. It was more efficacious than Benchmark in the SHP-77 model. No significant change in body weight was observed.

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HLX3901 Clinical Development Progress

China IND clearance:

March 2026

Current status:

FIH monotherapy dose escalation ongoing

FPI:

April 2026

Next phase:

Monotherapy **dose expansion and combination studies planned for Q2 2027***

Potential Future Indications:

- **1L ES-SCLC**
- **LS-SCLC without progression after concurrent chemoradiotherapy**

*Please refer to the company's announcement for the specific timeline.

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Q&A



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