HLX43 First-in-human Study Data Readout

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Sponsor Shanghai Henlius Biotech, Inc

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First Clinical-stage, Biomarker-independent ADC with IO Activity

A

Broad Therapeutic Effects

Outstanding efficacy in **IO&chemo treated** NSCLC:

Squamous NSCLC (≥ 4L)

- ORR: 28.6%
- Docetaxel failed (≥ 3L) ORR: 30%

EGFR WT Non-squamous NSCLC (≥ 3L)

- cORR: 46.7%
- 2.5 mg/kg cORR: 60%

B

Biomarker Independent

Efficacy in various types of NSCLC

- with or without *EGFR* mutation
- with or without brain metastasis
  - ➢ NSCLC with brain metastasis: cORR: 36.4% (4/11); DCR: 100%
- PD-L1 positive (TPS ≥1%, n=32) and negative (TPS <1%, n=21)

C

Favorable Safety Profile

Low hematologic toxicity (Grade ≥3 TRAE), supporting future expansion into 1L therapy and combination regimens

- Anemia 19.6%
- Neutrophil count decreased 16.1%
- Platelet count decreased 3.6%
- irAE indicating HLX43 is capable of eliciting immunotherapeutic effects

Potential of HLX43

HLX43 is an ADC with the potential for comprehensive coverage of cancer treatment and immunotherapy functionality.

Future Plans

HLX43 development in multiple tumor types and the exploration of various combination therapies.

ADC, antibody-drug conjugate; cORR, confirmed objective response rate; DXL, docetaxel; EGFR, epidermal growth factor receptor; ESCC, esophageal squamous cell carcinoma; IO, immunotherapy; irAE, immune-related adverse event; L, line; ORR, objective response rate; PD-L1, programmed cell death 1 ligand 1; NSCLC, non-small cell lung cancer; TRAE, treatment-related adverse event; WT, wild type.

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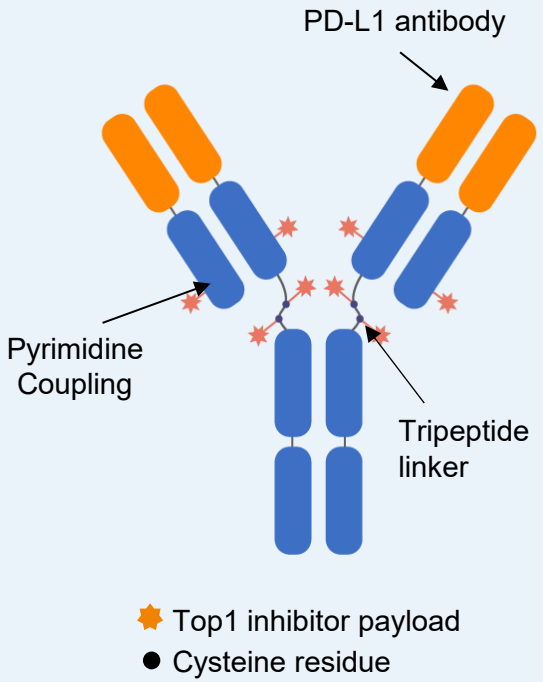
Background

- Despite the approval of multiple PD-1/PD-L1 inhibitors for advanced NSCLC, the majority of patients still face resistance, including both de novo and acquired resistance.[1,2].
- By specifically delivering cytotoxic payloads to tumor cells, antibody-drug conjugates (ADCs) represent an effective strategy for patients who are refractory to PD-1/PD-L1 therapies.[3]
- HLX43 is the second PD-L1-targeting ADC in global development.

Molecular components of HLX43



Key Features

- High-affinity, internalizable PD-L1 antibody
- Highly stable linker in circulating blood
- Cleavable and **TME-activatable tripeptide linker**
- Potent cytotoxic payload Top1 inhibitor (DAR=8)

1. Sharma P, et al. Cell. 2023;186(8):1652-1669. 2. Doroshow DB, et al. Nat Rev Clin Oncol. 2021;18(6):345-362. 3. Fu Z, et al. Sig Transduct Target Ther. 2022;7(1):93.
DAR, drug-to-antibody ratio; NSCLC, non-small-cell lung cancer; PD-L1, programmed cell death 1-ligand 1; PD-1, programmed cell death 1; TME, tumor microenvironment; Top1, topoisomerase 1.

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HLX43-FIH101 Study Design

cutoff date 2025/06/28

Key inclusion criteria

- Age ≥18 years
- ECOG PS 0 or 1
- For **phase 1a**, histologically or cytologically confirmed advanced malignant **solid tumors**
- For **phase 1b**, histologically or cytologically confirmed advanced **NSCLC** refractory or not amenable to standard therapy
- Measurable disease according to RECIST v1.1

Screening

CN only, 7 sites

- 4.0 mg/kg Q3W N=3-6
- 3.0 mg/kg Q3W N=3-6
- 2.5 mg/kg Q3W N=3-6
- 2.0 mg/kg Q3W N=3-6
- 1.0 mg/kg Q3W N=3-6
- 0.5 mg/kg Q3W N=3-6

Primary endpoints

- Proportion of patients with DLT
- MTD

CN only, 14 sites

Phase 1b: NSCLC

- 3.0 mg/kg Q3W N=20
- 2.5 mg/kg Q3W N=20
- 2.0 mg/kg Q3W N=20

Primary endpoints

- RP2D
- ORR

Leading Principal Investigator:
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Tenured Professor at Peking Union Medical College
President of the Shanxi Cancer Hospital

Leading Site: Cancer Hospital Chinese Academy of Medical Sciences

CN, China; ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors.

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Baseline demographic and disease characteristics

Here we present results in the NSCLC patients (phase 1a + phase 1b 2.0 and 2.5 mg/kg cohorts).

Data cutoff: Jun 28, 2025
Median follow-up:
9.0 months (95% CI 6.9–9.3)
ITT: N=56
SS: N=56
RES: N=54*

	NSCLC (n = 56)
Median age (range), years	60 (39–73)
Male, n (%)	38 (67.9)
ECOG PS, n (%)	
0	19 (33.9)
1	37 (66.1)
Smoking status, n (%)	
Never	31 (55.4)
Current	2 (3.6)
Former	23 (41.1)
NSCLC subtype	
Squamous	29 (51.8)
Docetaxel failed (≥ 3L)	10 (34.5)
Non-squamous	27 (48.2)
EGFR Wild type	15 (55.6)
EGFR Mutant	12 (44.4)
Metastases, n (%)	
Bone	14 (25.0)
Brain	11 (19.6)
Liver	4 (7.1)

	NSCLC (n = 56)
PD-L1 expression by TPS#, n (%)	
TPS ≥ 1%	32 (57.1)
TPS < 1%	23 (41.1)
Not available	1 (1.8)
Prior lines of therapy	
1	15 (26.8)
2	16 (28.6)
3	13 (23.2)
≥ 4	12 (21.4)
Median, range	2 (1–7)
Median, range for squamous	3 (1–7)
Median, range for non-squamous	2 (1–6)
EGFR Wild type	2 (1–6)
EGFR Mutant	2 (1–6)
Prior platinum-based chemo, n (%)	54 (96.4)
Prior immunotherapy, n (%)	50 (89.3)
Prior target therapy, n (%)	26 (46.4)
Prior docetaxel, n (%)	14 (25.0)

* Two patients without post-baseline tumor assessments were excluded from RES. # Detected with SP263.
CI, confidence interval; chemo, chemotherapy; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; ITT, intention-to-treat; NSCLC, non-small cell lung cancer; PD-L1, programmed cell death 1 ligand 1; PFS, progression-free survival; RES, response evaluable set; SS, safety set; TPS, tumor proportion score.

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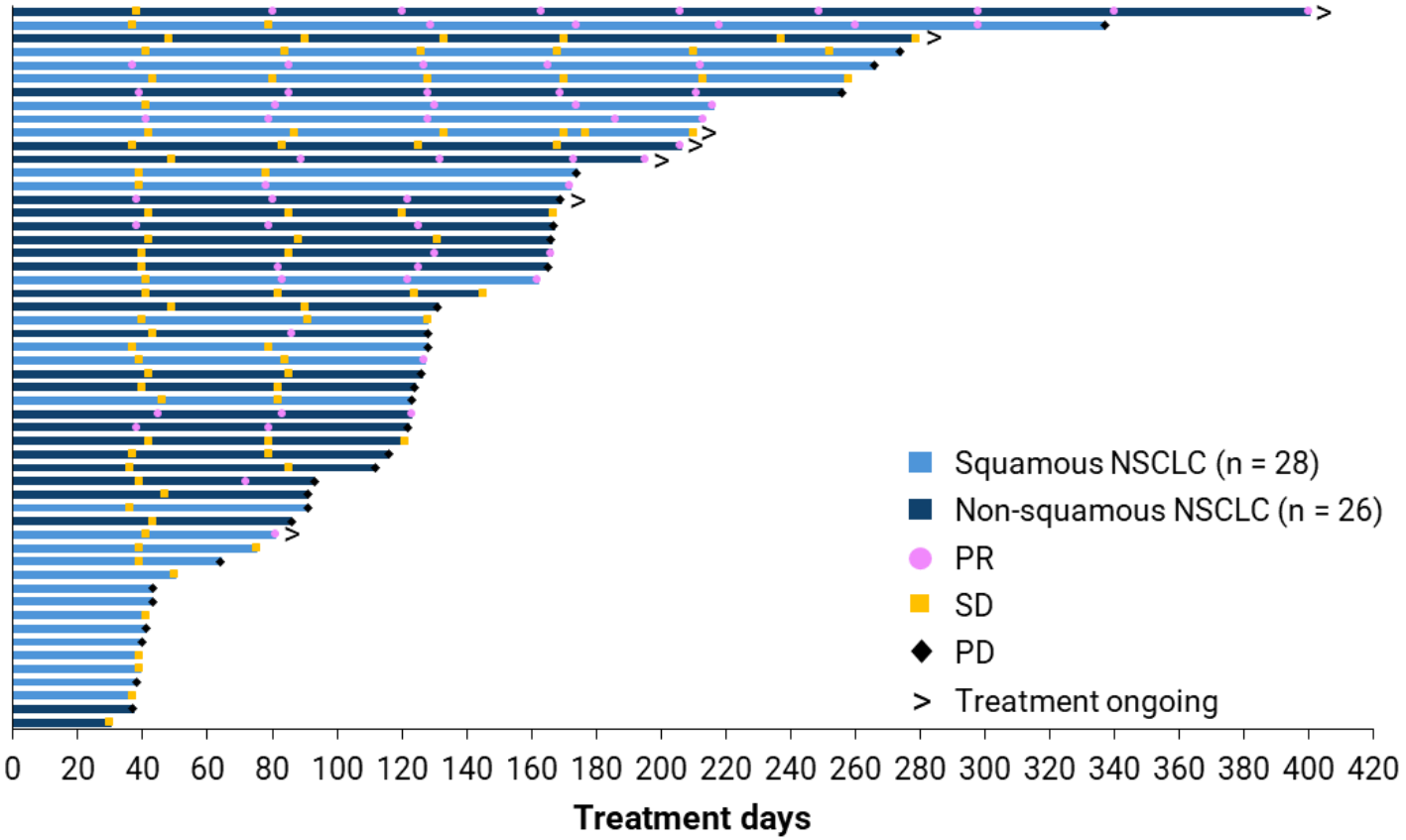
Efficacy in NSCLC patients per RECIST v1.1.

Efficacy*	NSCLC (n = 54)
CR, n (%)	0
PR, n (%)	20 (37.0)
SD, n (%)	27 (50.0)
PD, n (%)	6 (11.1)
NE, n (%)	1 (1.9)
ORR, % (95% CI)	37.0 (24.3–51.3)
DCR, % (95% CI)	87.0 (75.1–94.6)
mPFS, months (95% CI)	5.4 (4.0–5.8)
With brain metastasis (n=11)	5.4 (4.0–9.0)



* Unconfirmed tumor response among the 54 response-evaluable patients as assessed by investigator; 2 patients did not have post-baseline tumor assessment and were excluded in efficacy analysis.
CI, confidence interval; CR, complete response; DCR, disease control rate; mPFS, median progression-free survival; NE, not evaluable; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

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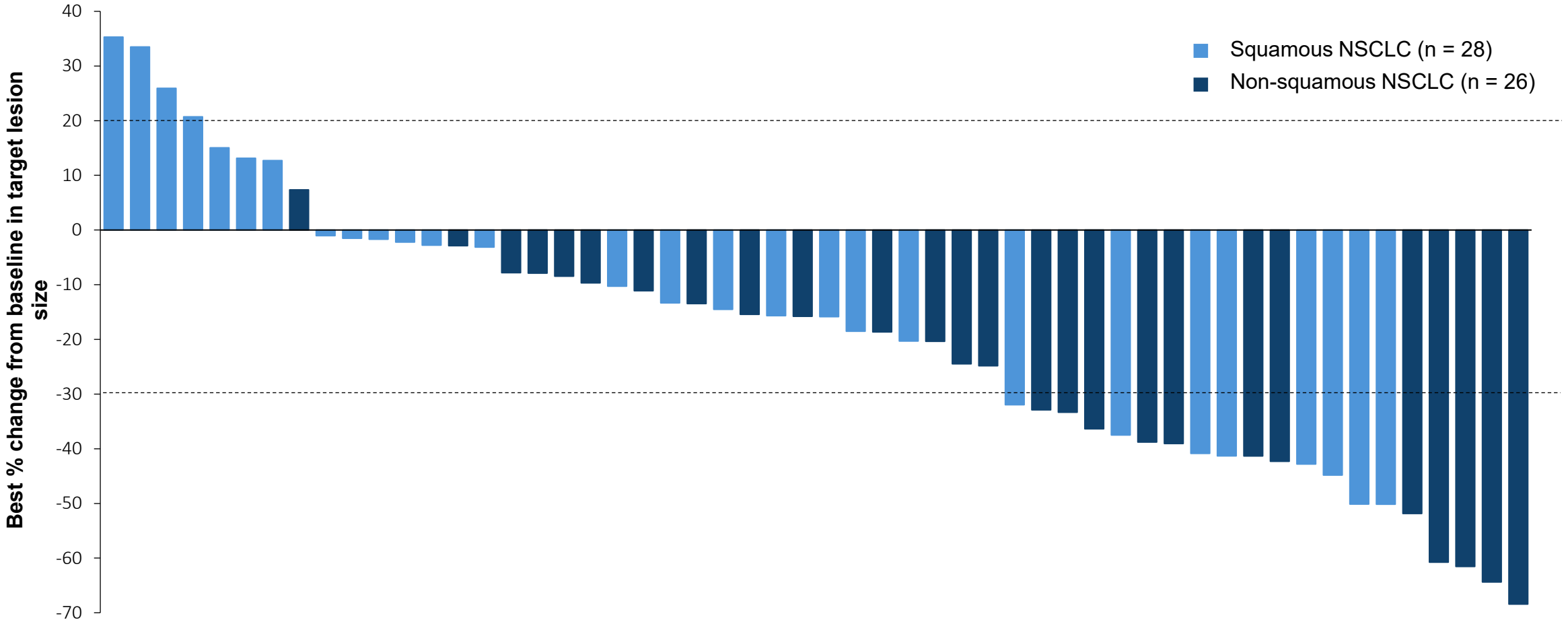
Tumor response in NSCLC patients per RECIST v1.1.



Tumor response among the 54 response-evaluable patients as assessed by investigator; 2 patients did not have post-baseline tumor assessment and were excluded in efficacy analysis.
NSCLC, non-small cell lung cancer; RECIST, Response Evaluation Criteria in Solid Tumors.

Subgroup analysis of tumor response per RECIST v1.1.

Tumor response*	ORR % (95% CI)	DCR % (95% CI)
NSCLC subtype		
Squamous (n = 28)	28.6 (13.2–48.7)	82.1 (63.1–93.9)
Docetaxel failed (≥ 3L) (n = 10)	30.0 (6.7–65.3)	80.0 (44.4–97.5)
2.0 mg/kg dose level (n = 15)	40.0 (16.3–67.7)	73.3 (44.9–92.2)
Non-squamous (n = 26)	46.2 (26.6–66.6)	96.2 (80.4–99.9)
EGFR Wild type (n = 15)	46.7 (21.3–73.4)#	93.3 (68.1–99.8)
2.5 mg/kg dose level (n = 5)	60.0 (14.7–94.7)#	80.0 (28.4–99.5)
EGFR Mutant (n = 11)	45.5 (16.7–76.6)	90.9 (58.7–99.8)
Brain metastasis		
Yes (n = 11)	36.4 (10.9–69.2)#	100 (71.5–100)
No (n = 43)	37.2 (23.0–53.3)	83.7 (69.3–93.2)
PD-L1 expression by TPS‡		
TPS ≥ 1% (n = 32)	34.4 (18.6–53.2)	87.5 (71.0–96.5)
TPS < 1% (n = 21)	38.1 (18.1–61.6)	85.7 (63.7–97.0)

* Unconfirmed tumor response assessed by investigator. # Confirmed tumor response as assessed by investigator. ‡ The PD-L1 expression level in one patient was not evaluable and was not included in the analysis.
CI, confidence interval; DCR, disease control rate; EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD-L1, programmed cell death 1 ligand 1; RECIST, Response Evaluation Criteria in Solid Tumors; TPS, tumor proportion score.

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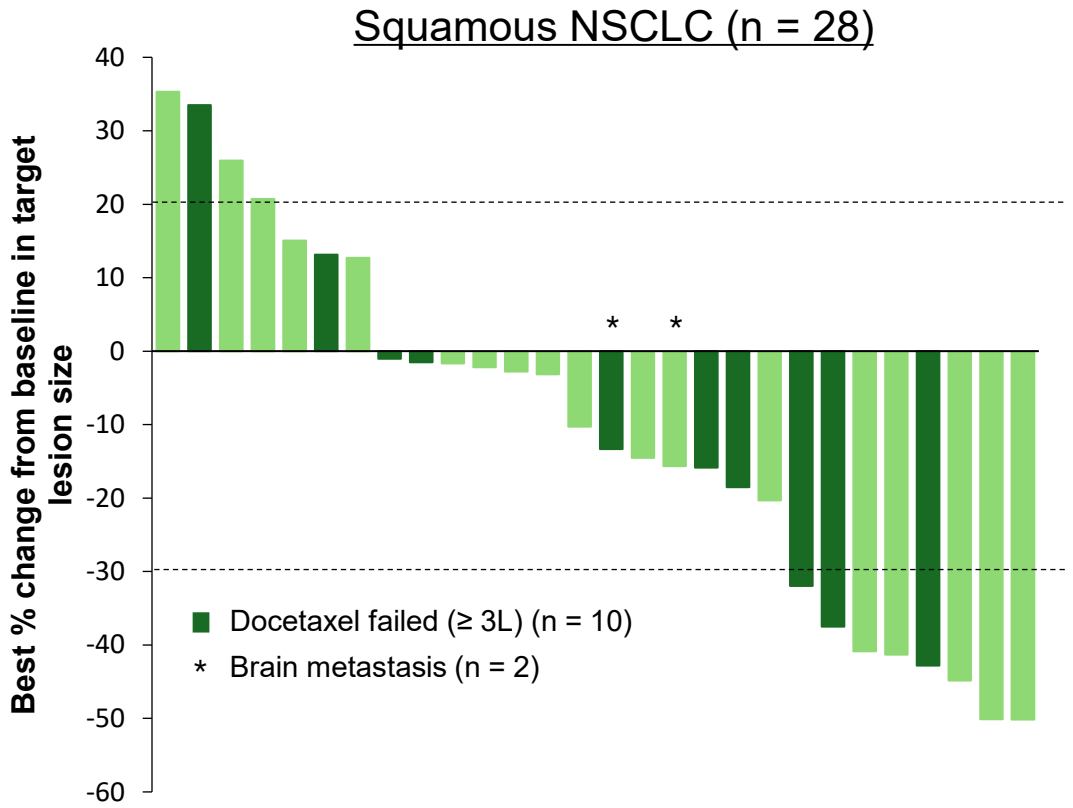
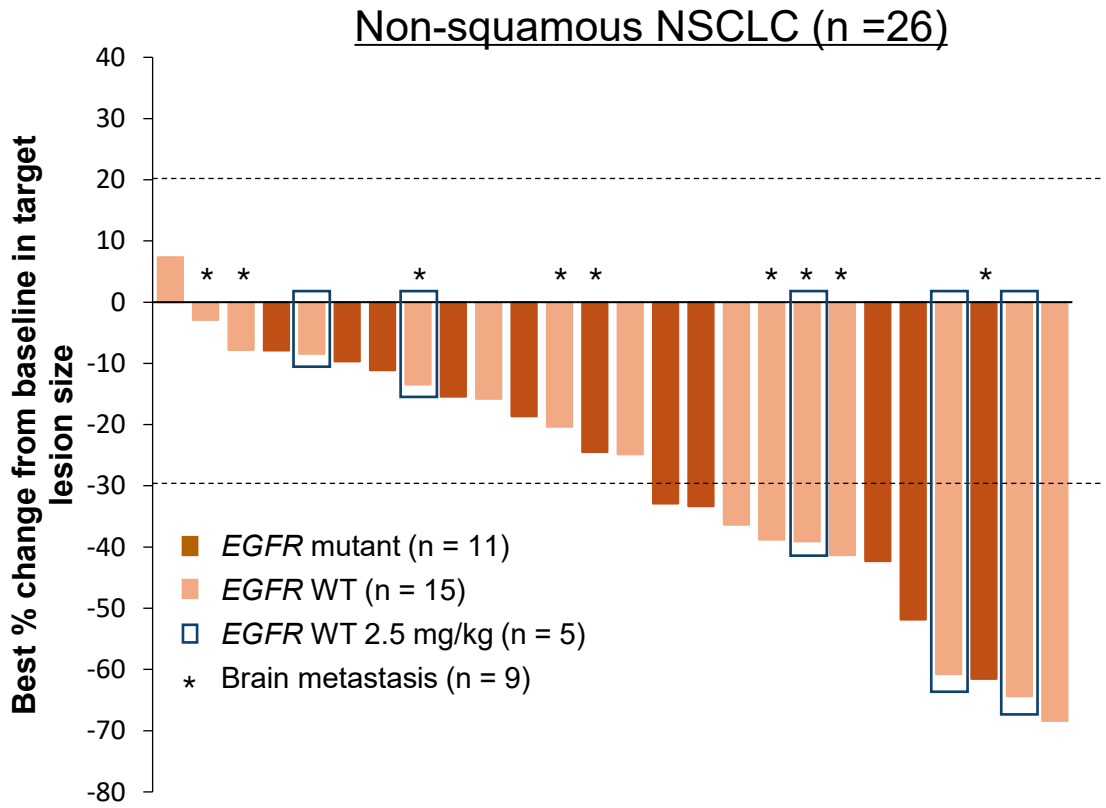
Subgroup analysis of tumor response per RECIST v1.1.



Docetaxel failed (≥ 3L): ORR 30.0% (95 CI 6.7–65.3)
DCR 80.0% (95 CI 44.4–97.5)

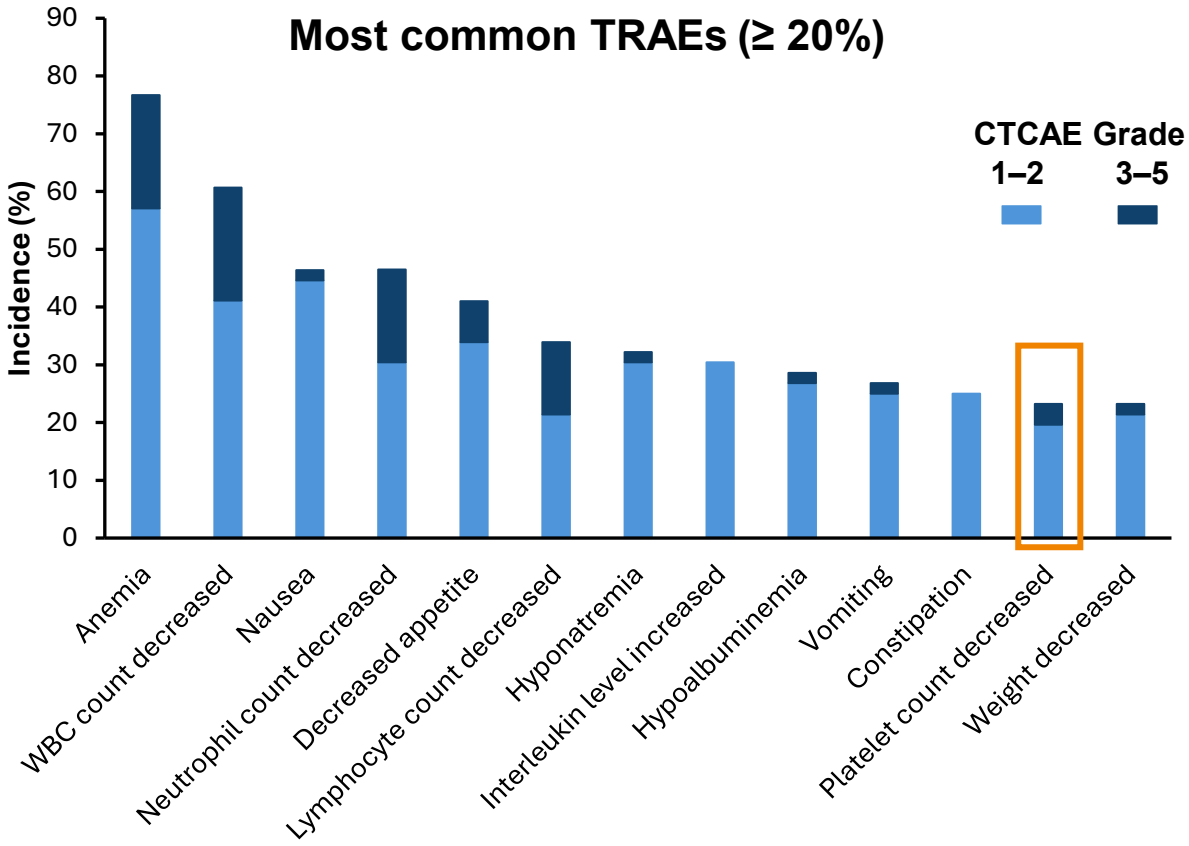


EGFR WT 2.5 mg/kg: cORR 60.0% (95 CI 14.7–94.7)
DCR[#] 80.0% (95 CI 28.4–99.5)

Tumor response among the 54 response-evaluable patients as assessed by investigator; 2 patients did not have post-baseline tumor assessment and were excluded in efficacy analysis.
[#] 1 case of stable disease did not meet the requirement of minimum evaluation duration and was counted as not evaluable in tumor assessment.
cORR, confirmed objective response rate; DCR, disease control rate; EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; ORR, objective response rate; RECIST, Response Evaluation Criteria in Solid Tumors; WT, wild type.

Safety and tolerability

Safety*	NSCLC (n = 56)
Any TRAE, n (%)	56 (100)
Grade ≥3	26 (46.4)
Most common Grade ≥3 (≥ 10%)	
Anemia	11 (19.6)
WBC count decreased	11 (19.6)
Neutrophil count decreased	9 (16.1)
Lymphocyte count decreased	7 (12.5)
TRAE leading to Tx interruption, n (%)	24 (42.9)
TRAE leading to Tx discontinuation, n (%)	5 (8.9)
TRAE leading to Tx reduction, n (%)	10 (17.9)
TRAE leading to death, n (%)	1 (1.8)#



* Interstitial lung disease was reported in 2 patients as grade 3; both are in recovery. # From 2.5 mg/kg cohort (squamous NSCLC): respiratory failure.
CTCAE, Common Terminology Criteria for Adverse Events; TRAE, treatment-related adverse event; Tx, treatment; WBC, white blood cell.

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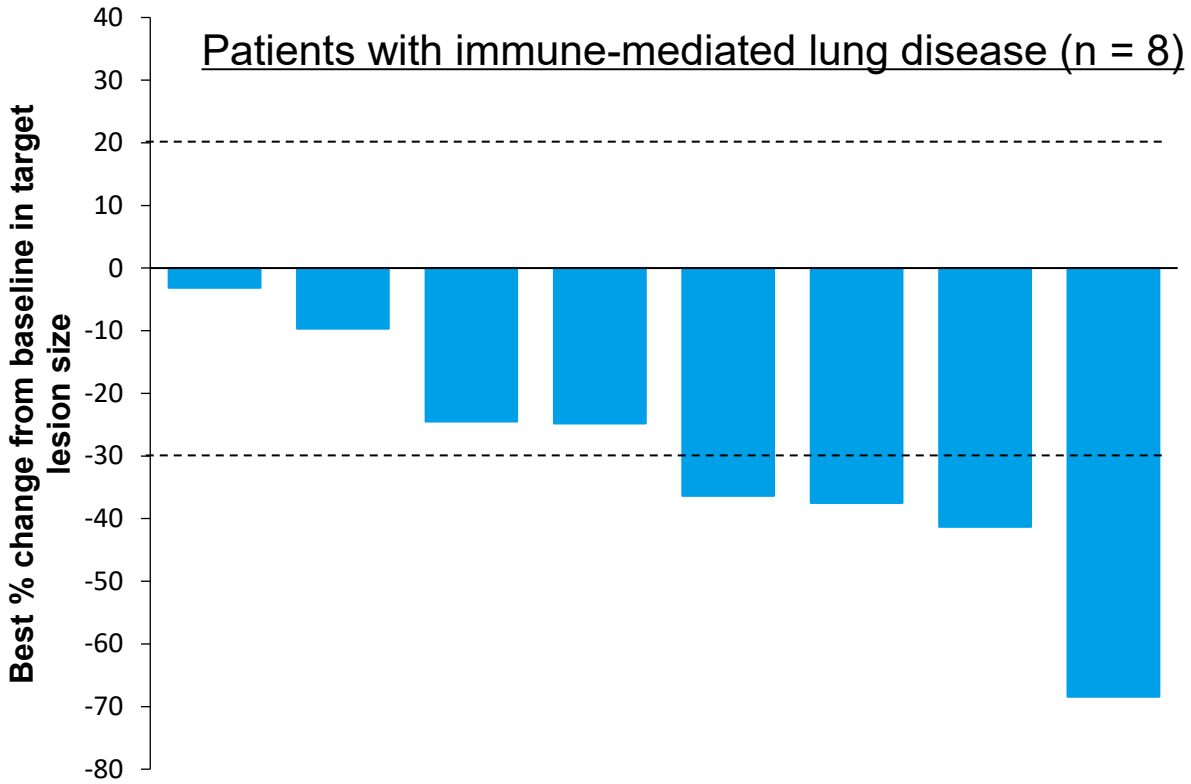
Immune-related adverse events

	NSCLC (n = 56)
Any irAE, n (%)	12 (21.4)
Most common irAEs (≥ 10%)	
Immune-mediated lung disease	8 (14.3)
Grade 2	3 (5.4)
Grade 3	4 (7.1)
Grade 4	1 (1.8)
Grade 5	0

Confirmed ORR of 50% and 100% tumor shrinkage in patients with immune-mediated lung disease indicated that **HLX43 is capable of eliciting immunotherapeutic effects** in addition to payload-mediated cytotoxic tumor cell killing.



irAE, immune-related adverse event; ORR, objective response rate.

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Conclusions

- **Outstanding efficacy in NSCLC**
  - ✓ **IO- and chemo-treated Squamous NSCLC (≥ 4L)**
    - ✓ ORR: 28.6%
    - ✓ Docetaxel failed (≥ 3L) ORR: 30%
  - ✓ **IO- and chemo-treated, *EGFR* WT Non-squamous NSCLC (≥ 3L)**
    - ✓ cORR: 46.7%
    - ✓ 2.5 mg/kg cORR: 60%
  - ✓ **NSCLC with brain metastasis:** cORR 36.4% (4/11); DCR 100%
- **Biomarker independent:** efficacy observed irrespective of *EGFR* mutation status or PD-L1 expression level
- **Favorable safety profile with low hematologic toxicities**

HLX43 demonstrated promising efficacy along with manageable safety in advanced or metastatic NSCLC. Further investigation of HLX43 for this disease indication is warranted.

chemo, chemotherapy; cORR, confirmed objective response rate; DCR, disease control rate; EGFR, epidermal growth factor receptor; IO, immunotherapy; L, line; NSCLC, non-small-cell lung cancer; ORR, objective response rate; PD-L1, programmed cell death 1 ligand 1; WT, wild type.

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HLX07HLX10-sqNSCLC201 Study Data Readout

Presenter Dr. Qingyu Wang, General Manager of Clinical Development & China CMO

Date September 06, 2025

Sponsor Shanghai Henlius Biotech, Inc

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Background

- Immunotherapy (PD-L1/PD-1 inhibitors) combined with chemotherapy has demonstrated efficacy and been approved as first-line treatment for advanced squamous non-small cell lung cancer (sqNSCLC)[1,2]. However, the prognosis remains unsatisfactory.
- EGFR is often overexpressed in advanced NSCLC[3,4], suggesting the potential of targeting this pathway in this disease indication.

- This randomized, multicenter phase 2 study evaluated the efficacy and safety of HLX07, a novel humanized anti-EGFR monoclonal antibody, plus serplulimab (anti-PD-1 antibody) and chemotherapy as first-line treatment for advanced sqNSCLC.

Previous analysis presented at the 2025 ASCO Annual Meeting showed encouraging efficacy of the tri-combination regimen. Here we report an updated analysis of the efficacy and safety findings.

1. Paz-Ares L, et al. N Engl J Med 2018;379(21):2040-2051. 2. Guo H, et al. Medicine (Baltimore) 2024;103(3):e36861. 3. Al Olayan A, et al. J Infect Public Health 2012; 5 Suppl 1:S50-S60. 4. Wang Z, et al. Methods Mol Biol 2017;1652:3-35.
EGFR, epidermal growth factor receptor; NSCLC, non-small-cell lung cancer; PD-L1, programmed cell death-ligand 1; PD-1, programmed death-1; sqNSCLC, squamous non-small-cell lung cancer.

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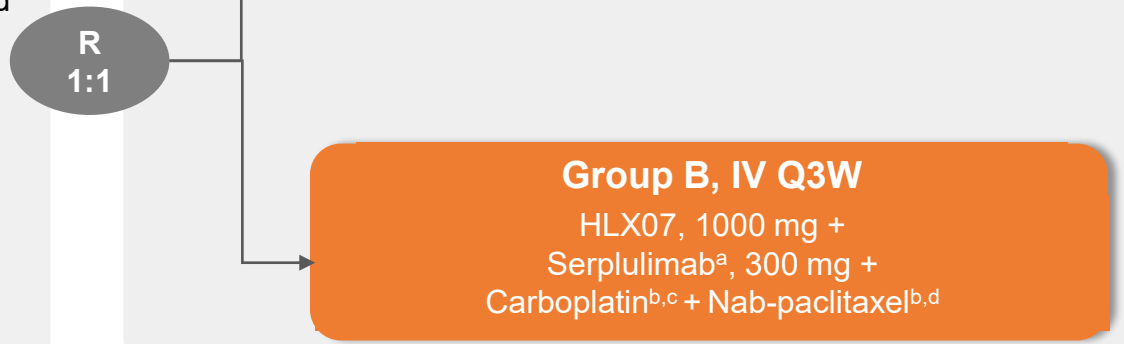
Study design

A randomized, multicenter phase 2 study (NCT04976647).

Key inclusion criteria:

- Aged ≥18 years;
- ECOG PS of 0 or 1;
- Histologically confirmed stage IIIB/IIIC or IV (AJCC 8th edition) sqNSCLC that could not be treated with surgery or radiation therapy;
- No prior systemic antitumor therapy;
- Provision of tumor tissue for determination of EGFR and PD-L1 expression levels; EGFR H-score ≥150 as confirmed by central laboratory.



Treatment regimen

Study Endpoints

Primary endpoints

- ORR
- PFS

Assessed by BICR per RECIST v1.1.

Secondary endpoints

- OS
- DoR, DCR
- Safety
- PK; immunogenicity;
- Biomarkers; QoL

[a] Up to 2 years; [b] 4–6 cycles; [c] Carboplatin: area under curve 5 (maximum dosage 750 mg) or area under curve 6 (maximum dosage 900 mg); [d] Nab-paclitaxel: 260 mg/m^2.

AJCC, American Joint Committee on Cancer; BICR, blinded independent central review; DCR, disease control rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; IV, intravenous; ORR, objective response rate; OS, overall survival; PD-L1, programmed cell death-ligand 1; PFS, progression-free survival; PK, pharmacokinetics; Q3W, every 3 weeks; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors; sqNSCLC, squamous non-small-cell lung cancer.

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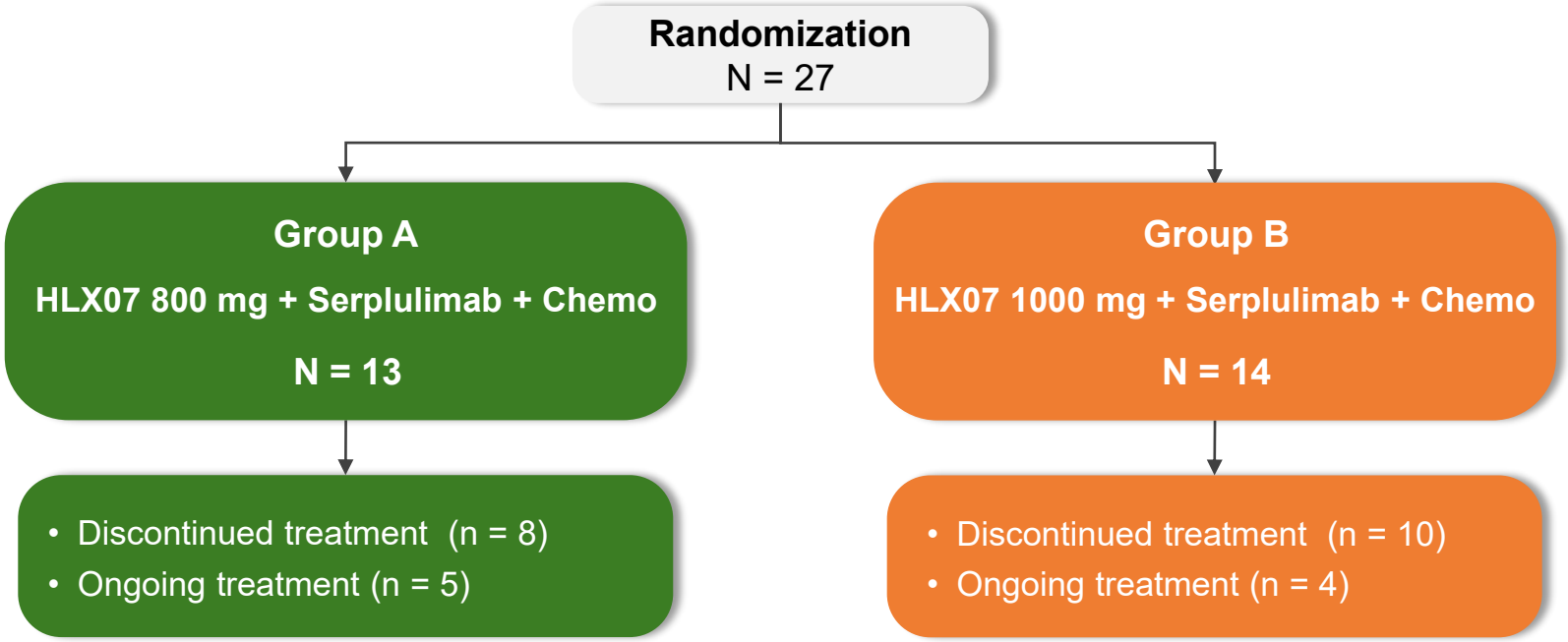
Patient disposition

Data cutoff: March 05, 2025
Median follow-up: 18.6 months (95% CI 17.2–23.4)
ITT: 27 patients
SS: 27 patients



Chemo, chemotherapy; CI, confidence interval; ITT, intention-to-treat; SS, safety set.

Baseline demographics and disease characteristics

	Group A (n = 13)	Group B (n = 14)
Median age (range), years	65 (54–80)	66 (50–72)
Sex, n (%)		
Male	11 (84.6)	12 (85.7)
Female	2 (15.4)	2 (14.3)
ECOG PS, n (%)		
0	3 (23.1)	3 (21.4)
1	10 (76.9)	11 (78.6)
Tumor stage, n (%)		
IIIB/C	5 (38.5)	7 (50.0)
IV	8 (61.5)	7 (50.0)

	Group A (n = 13)	Group B (n = 14)
Site of metastases		
Bone	2 (15.4)	1 (7.1)
Brain	0	1 (7.1)
Liver	1 (7.1)	0
PD-L1 expression*, TPS, n (%)		
TPS < 1%	8 (61.5)	6 (42.9)
1% ≤ TPS < 50%	3 (23.1)	5 (35.7)
TPS ≥ 50%	2 (15.4)	3 (21.4)
EGFR expression, H-score		
H-score < 200, n (%)	7 (53.8)	7 (50.0)
H-score ≥ 200, n (%)	6 (46.2)	7 (50.0)
Median	190.0	202.5
Range	150–275	155–290

*Detected with 22C3.
ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; PD-L1, programmed death-ligand 1; TPS, tumor proportion score;

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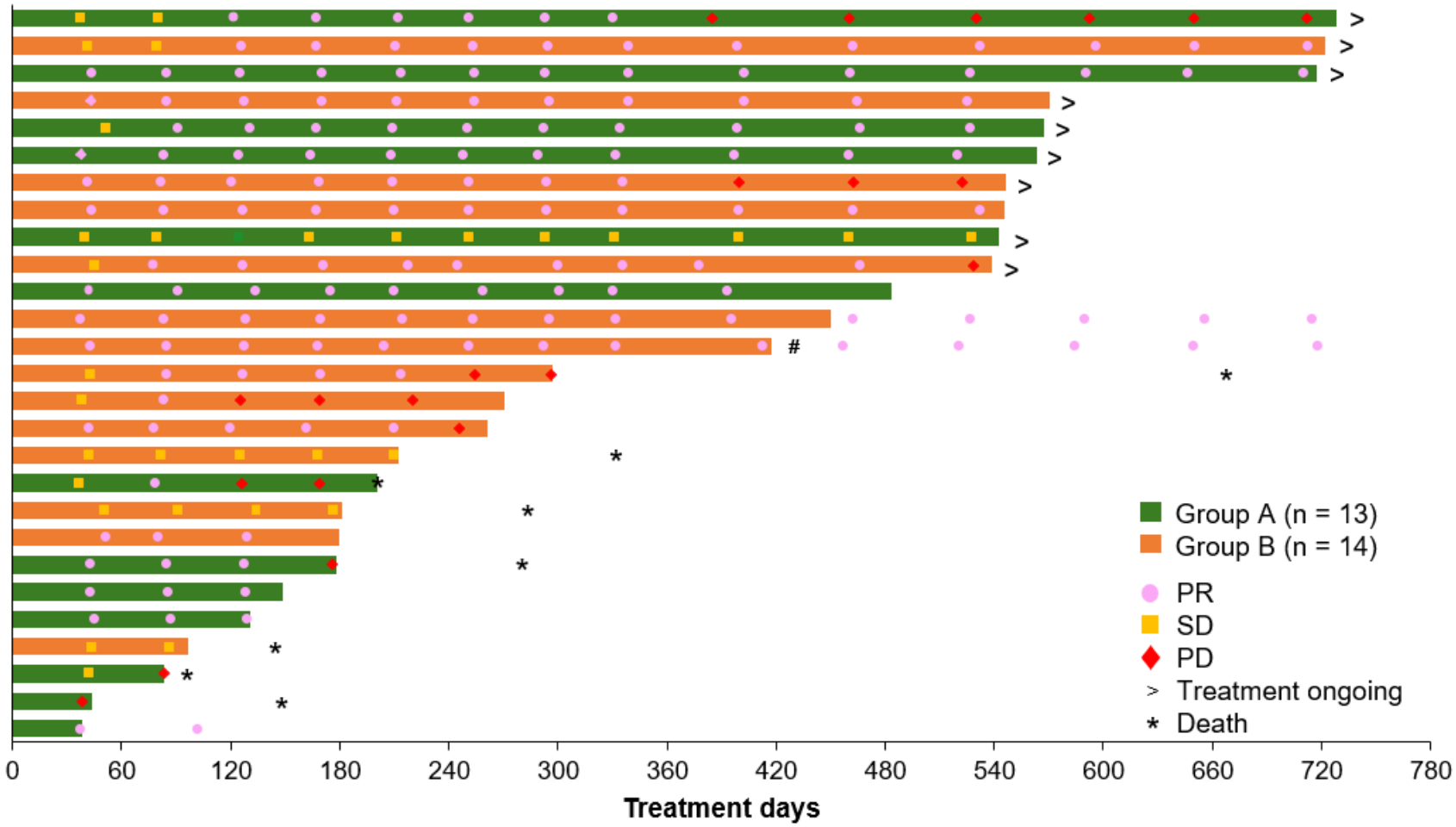
Primary endpoint: BICR-assessed ORR per RECIST v1.1

Endpoint (according to BICR assessments)	Group A (n = 13)	Group B (n = 14)
Confirmed tumor response[#]		
CR, n (%)	0	0
PR, n (%)	9 (69.2)	10 (71.4)
SD, n (%)	3 (23.1)	4 (28.6)
PD, n (%)	1 (7.7)	0
NE, n (%)	0	0
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)

As of data cutoff date, overall survival and median DoR were not reached in either group and will be presented in subsequent reports.

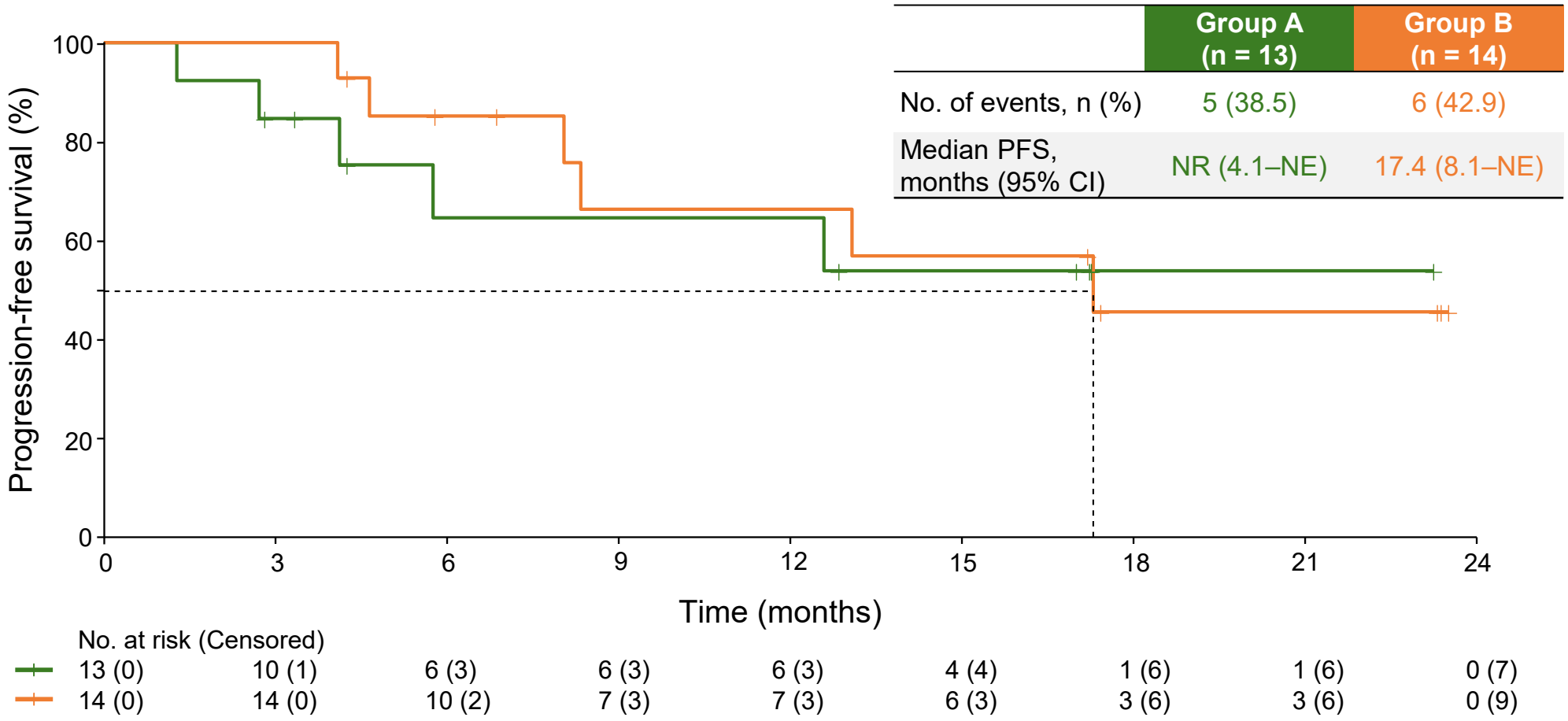
BICR, blinded independent central review; CI, confidence interval; CR, complete response; DCR, disease control rate; DoR, duration of response; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

Duration of response as assessed by BICR per RECIST v1.1



#The patient with brain metastasis had a partial response at the first tumor assessment (with disappearance of the brain metastases) and a duration of response of over 21 months.
BICR, blinded independent central review; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

Primary endpoint: BICR-assessed PFS



BICR, blinded independent central review; CI, confidence interval; NE, not evaluable; NR, not reached; No., number; PFS, progression-free survival.

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Safety summary

Adverse event, n (%)	Group A (n = 13)	Group B (n = 14)
Any TEAEs	13 (100.0)	14 (100.0)
≥ Grade 3	13 (100.0)	13 (92.9)
Grade 3	6 (46.2)	11 (78.6)
Grade 4	6 (46.2)	2 (14.3)
Grade 5	1 (7.7)[a]	0
Leading to HLX07 or serplulimab discontinuation	3 (23.1)[b]	3 (21.4)[c]
Any TRAEs	13 (100.0)	14 (100.0)
HLX07 or serplulimab-related	13 (100.0)	14 (100.0)
≥ Grade 3	12 (92.3)	10 (71.4)
Grade 3	7 (53.8)	9 (64.3)
Grade 4	4 (30.8)[d]	1 (7.1)[e]
Grade 5	1 (7.7)[a]	0
Any AESIs	12 (92.3)	14 (100.0)
IRR	1 (7.7)	2 (14.3)
irAE	6 (46.2)	8 (57.1)
Rash (HLX07-related)	6 (46.2)	8 (57.1)
Hypomagnesemia (HLX07-related)	6 (46.2)	6 (42.9)
Serious	1 (7.7)	2 (14.3)

Most common grade ≥ 3 TEAEs (≥ 10% in either group)

n (%)	Group A (n = 13)	Group B (n = 14)
Neutrophil count decreased	7 (53.8)	9 (64.3)
White blood cell count decreased	7 (53.8)	5 (35.7)
Platelet count decreased	4 (30.8)	5 (35.7)
Anemia	4 (30.8)	3 (21.4)
Pneumonia	4 (30.8)	3 (21.4)
Hypokalemia	2 (15.4)	5 (35.7)
Hypomagnesemia	2 (15.4)	2 (14.3)
Hypocalcemia	2 (15.4)	1 (7.1)
Dermatitis acneiform	1 (7.7)	2 (14.3)
Lymphocyte count decreased	1 (7.7)	2 (14.3)
Rash	1 (7.7)	2 (14.3)

[a]death related to both HLX07 and serplulimab with preferred term of pneumonia. [b]discontinuation of HLX07 and serplulimab occurred for two patients: one with pneumonia (grade 5) and one with hemoptysis (grade 2); discontinuation of serplulimab occurred for another patient with dermatitis and cellulitis (both grade 3). [c]discontinuation of HLX07 and serplulimab occurred for two patients: one with palmar-plantar erythrodysesthesia syndrome (grade 3) and one with supraventricular extrasystoles (grade 2); discontinuation of serplulimab occurred for another patient with sicca syndrome (grade 3). [d]two patients with TRAEs related to both HLX07 and serplulimab with preferred term of platelet count decreased, and neutrophil count decreased, respectively; one patient with TRAE related to HLX07 with preferred term of hypomagnesemia; one patient with TRAE related to serplulimab with preferred term of neutrophil count decreased. [e]related to HLX07 but not serplulimab with preferred term of hypomagnesemia.

AESI, adverse event of special interest; irAE, immune-related adverse event; IRR, infusion-related reaction; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

Conclusions

- Encouraging antitumor activity of HLX07 (HLX07 **800** mg and **1000** mg) + serplulimab + chemo
  - BICR-assessed confirmed ORR: **69.2%** and **71.4%**;
  - BICR-assessed confirmed DCR: **92.3%** and **100.0%**;
  - BICR-assessed median PFS: **not reached** and **17.4** months;
  - OS and median DoR not reached in both groups;
- Both investigated treatment regimens had manageable safety profiles.

Tri-combination therapy of HLX07, serplulimab and chemotherapy demonstrated encouraging efficacy along with manageable safety profile for patients with advanced sqNSCLC. Further investigation of this treatment regimen as first-line therapy is warranted.

DCR, disease control rate; DoR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; sqNSCLC, squamous non-small-cell lung cancer.

Thanks!

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