HLX43 First -in -human Study Data Readout

Presenter Dr. Qingyu W

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HLX43-FIH101 Study Design

cutoff date 2025/03/28

Key inclusion criteria

- $ J H • \ H D U V
- ECOG PS 0 or 1.
- For phase 1a, histologically or cytologically confirmed advanced/metastatic malignant solid tumors .
- For phase 1b , histologically or cytologically confirmed advanced/metastatic NSCLC refractory or not amenable to standard therapy.
- Measurable disease according to RECIST v1.1.

Screening

Phase 1a: solid tumor

- 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

CN only, 7 sites

Phase 1b: NSCLC

- 3.0 mg/kg Q3W NSCLC, N=21
- 2.5 mg/kg Q3W NSCLC, N=22
- 2.0 mg/kg Q3W NSCLC, N=21

CN only, 14 sites

Leading Principle Investigator:

Dr. Jie Wang

Director of Medical Oncology Department, Cancer Hospital Chinese Academy of Medical Sciences

Tenured Professor at Peking Union Medical College

President of the Shanxi Cancer Hospital

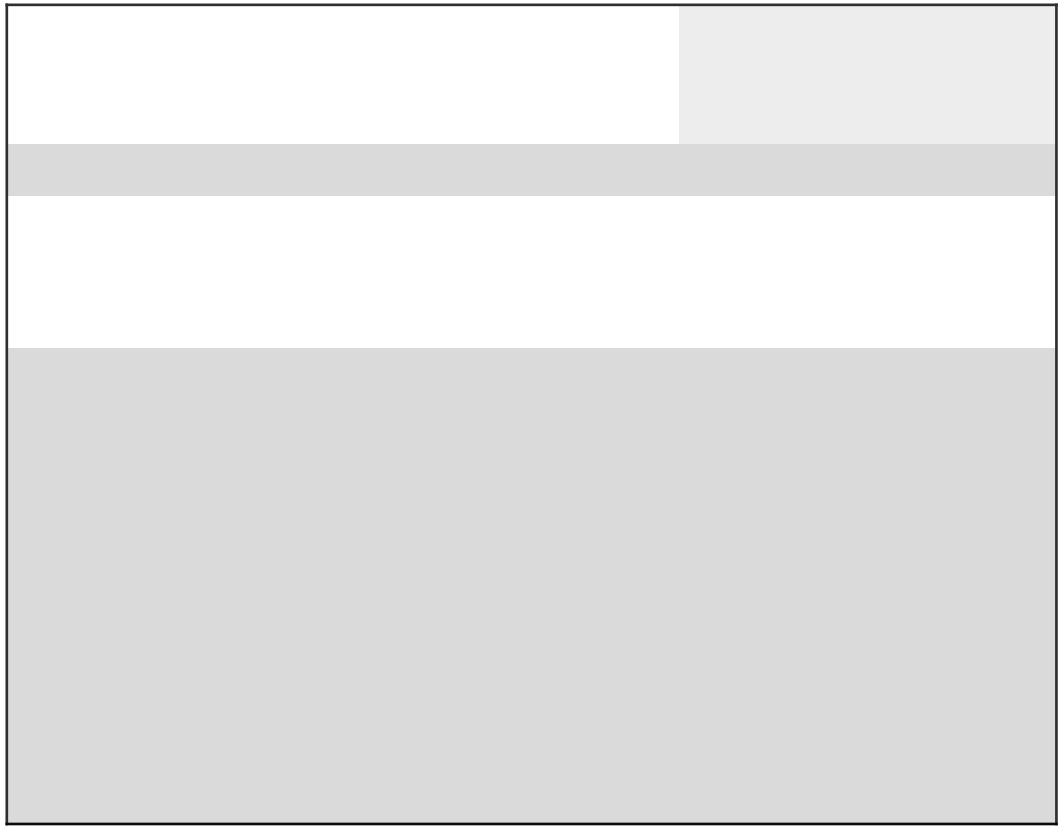
Leading Site: Cancer Hospital Chinese Academy of Medical Sciences

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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HLX43 Ph 1a Dose Escalation – Patient Demographics and Baseline Characteristics

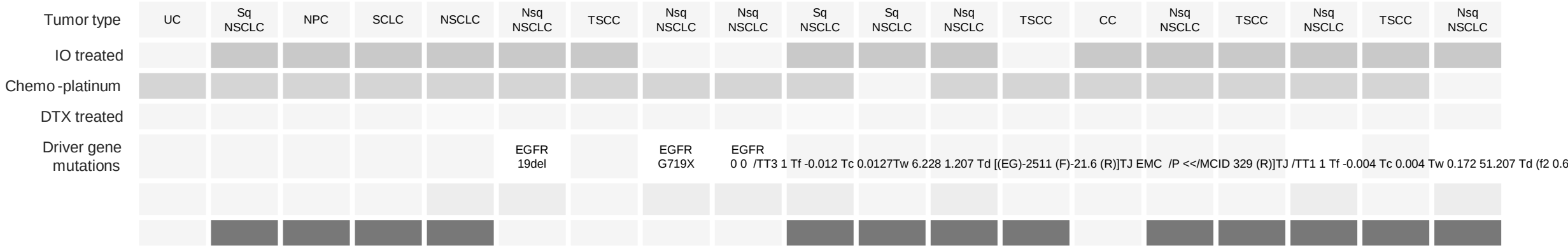
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HLX43 Ph 1a Dose Escalation Efficacy Data

cutoff date 2025/03/28



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HLX43 Ph 1a Dose Escalation Safety Data

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Median follow-up duration: 9.7 months

Summary of adverse events, n (%)	Phase 1a (n = 21)
Any TEAE*	21 (100)
• * U D3G H	10 (47.6)
• * U D G H •	
Neutrophil count decreased	5 (23.8)
White blood cell count decreased	5 (23.8)
Anemia	3 (14.3)
Pneumonia	3 (14.3)
Serious	10 (47.6)
Any TRAE	20 (95.2)
• * U D3G H	6 (28.6)
TEAE leading to Tx interruption	9 (42.9)
TEAE leading to Tx discontinuation	4 (19.0)
TEAE leading to dose reduction	8 (38.1)
TEAE leading to death	4 (19.0)

0 R V W F R P P R Q 7 ($ (V • Q	Phase 1a (n = 21)
Anemia	16 (76.2)
Interleukin level increased	13 (61.9)
White blood cell count decreased	11 (52.4)
Neutrophil count decreased	10 (47.6)
Hyponatremia	10 (47.6)
Nausea	9 (42.9)
Hypoalbuminemia	9 (42.9)
Hyperuricemia	8 (38.1)
Aspartate aminotransferase increased	5 (23.8)
Lymphocyte count decreased	5 (23.8)
Hypochloremia	5 (23.8)

*No infusion-related reaction was reported in this study.

TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; Tx, treatment.

DLT: One patient in the 4 mg/kg dose group in phase 1a experienced DLTs of febrile neutropenia and decreased white blood cell count; MTD was 4 mg/kg.

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HLX43--

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HLX43 Ph 1b 2.0mg/kg Efficacy Data

cutoff date 2025/03/28

Median follow-up duration: 7.0 months

Tumor response per RECIST v1.1 [a]	Phase 1b 2.0 mg/kg (n = 21)
CR, n (%)	0
PR, n (%)	8 (38.1)
SD, n (%)	9 (42.9)
PD, n (%)	4 (19.0)
NE, n (%)	0
ORR, % (95% CI)	38.1 (18.1–61.6)
Confirmed ORR, % (95% CI)	33.3 (14.6–57.0)
2 5 5 L Q S D W L H Q W V Z K R K D G • S U L R U lines of therapy, %	38.5 (5/13)
DCR, % (95% CI)	81.0 (58.1–94.6)
mDOR, months (95% CI)	NR (1.4–NE)
mPFS, months (95% CI)	5.4 (4.0–6.3)
mOS, months (95% CI)	NR (6.7–NE)

Subgroup analysis of tumor response per RECIST v1.1[a]	ORR % (95% CI)	DCR % (95% CI)
NSCLC subtype		
Squamous (n = 15)	40.0 (16.3–67.7)	73.3 (44.9–92.2)
Confirmed response	33.3 (11.8–61.6)	73.3 (44.9–92.2)
Nonsquamous (n = 6)	33.3 (4.3–77.7)	100 (54.1–100)
Confirmed response	33.3 (4.3–77.7)	100 (54.1–100)
Used docetaxel		
Yes (n = 9)	33.3 (7.5–70.1)	77.8 (40.0–97.2)
No (n = 12)	41.7 (15.2–72.3)	83.3 (51.6–97.9)
Brain metastasis		
Yes (n = 6)	33.3 (4.3–77.7)	100 (54.1–100)
No (n = 15)	40.0 (16.3–67.7)	73.3 (44.9–92.2)
Liver metastasis		
Yes (n = 3)	33.3 (0.8–90.6)	66.7 (9.4–99.2)
No (n = 18)	38.9 (17.3–64.3)	83.3 (58.6–96.4)
PD-L1 expression		
& 3 6 • Q	37.5 (15.2–64.6)	81.3 (54.4–96.0)
CPS < 1 (n = 5)	40.0 (5.3–85.3)	80.0 (28.4–99.5)

[a] Unconfirmed tumor response assessed by investigator.

CI, confidence interval; CPS, combined positive score; CR, complete response; DCR, disease control rate; mDOR, median duration of response; mPFS, median progression-free survival; mOS, median overall survival; NE, not evaluable; NR, not reached; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD, progressive disease; PD-L1, programmed death-ligand 1; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

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[a] In efficacy-evaluable patients.

ALK, anaplastic lymphoma kinase; CPS, combined positive score; DTX, docetaxel; ERBB2, Erb-B2 receptor tyrosine kinase; KRAS, Kirsten rat sarcoma viral oncogene homolog; NSCLC, non-small cell lung cancer; nsqNSCLC, nonsquamous NSCLC; PD-L1, programmed death-ligand 1; sqNSCLC, squamous NSCLC; TKI, tyrosine kinase inhibitor.

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HLX43 Ph 1b 2.0mg/kg Safety Data

cutoff date 2025/03/28

Summary of adverse events, n (%)	Phase 1b 2.0 mg/kg

* No infusion-related reaction was reported in this study .

** No Grade 3 or higher platelet count decreased was reported ; only 3 patients (14.3%, 3/21) experienced Grade 1 platelet count decreased .

TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; Tx, treatment.

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

A

Broad Therapeutic Effects

B

C

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, including combining it with serplulimab

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