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PT2.01.03: First-in-Human Phase I Study of ALK202, a Novel EGFR/c-MET Bispecific Antibody–Drug Conjugate, in Patients with Advanced Solid Tumors

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INTRODUCTION & METHODS

- ALK202 is a first-in-class bispecific antibody–drug conjugate (ADC) targeting EGFR and c-MET, linked to topoisomerase I inhibitor Exatecan via a cleavable and highly hydrophilic linker.
- ALK202-01 is an open-label, multicenter, phase I study (NCT06707610) enrolling patients with advanced solid tumors refractory to standard therapy (Figure 1).
- Dose escalation (Part A), guided by a Bayesian optimal interval (BOIN) design, evaluated ALK202 at doses of 1.5–6.4 mg/kg administered every 3 weeks (Q3W) and 3.2–3.6 mg/kg administered on Days 1 and 8 every 3 weeks (D1/D8 Q3W).
- Dose-expansion cohorts (Part B) will assess selected doses (2.8 or 3.2 mg/kg D1/D8 Q3W) in EGFRmut NSCLC and other solid tumors.

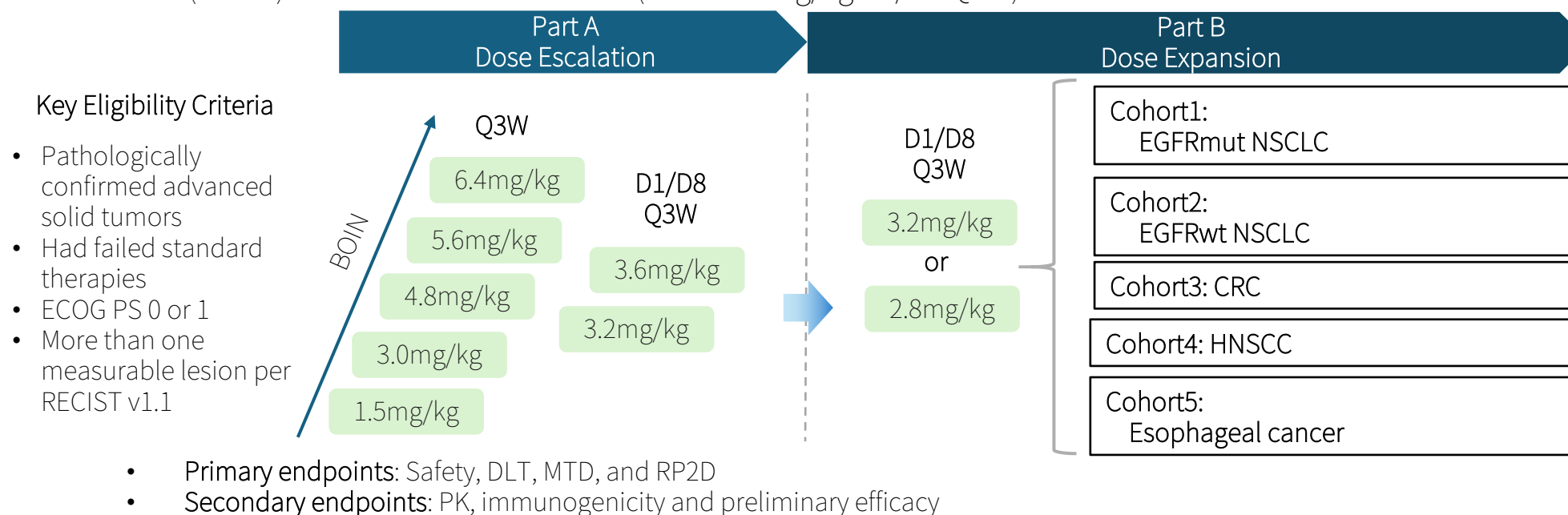


Figure 1. ALK202-01 Study design

Patient Baseline and Safety Profile

- As of June 24th, 2026, 71 patients (Table 1) were enrolled. 96% (68/71) of the patients experienced treatment-related adverse events (TRAE) and 31% (22/71) of the patients experienced TRAE of Grade ≥ 3 . The overall incidence of adverse events is summarized in Table 2.
- The most common TEAEs in $\geq 15\%$ of patients were hematologic and gastrointestinal toxicities (Table 3).

Table 1. Baseline Characteristics

Patient Characteristics	Total (N=71)
Age, median (range), years	61 (33-80)
Gender, n (%)	
Male	38 (54%)
Race, n (%)	
Asian	58 (82%)
White	8 (11%)
Other	5 (7%)
ECOG PS, n (%)	
0	9 (13%)
1	62 (87%)
Metastatic, n (%)	
Yes	64 (90%)
Prior lines, n (%)	
1	13 (18%)
2	20 (28%)
≥ 3	38 (54%)

Table 2. Overall Safety Profile

Adverse Events n (%)	Total (N=71)
Any Grade	71 (100%)
Treatment-related	68 (96%)
Grade ≥ 3 TEAEs	29 (41%)
Treatment-related	22 (31%)
SAEs	18 (25%)
Treatment-related	12 (17%)
TRAEs leading to interruption	29 (41%)
TRAEs leading to reduction	17 (24%)
TRAEs leading to discontinuation	2 (3%)

Table 3. TEAE by PT ($\geq 15\%$)

Adverse Event Term, n (%)	All (n=71)	
	All Grade	$\geq$ Grade 3
Decreased appetite	38 (54%)	0
Anaemia	36 (51%)	6 (9%)
Fatigue	34 (48%)	1 (1%)
Nausea	29 (41%)	1 (1%)
Vomiting	28 (39%)	0
Weight decreased	28 (39%)	0
Neutrophil count decreased	26 (37%)	13 (18%)
White blood cell count decreased	24 (34%)	4 (6%)
Hypoalbuminaemia	23 (32%)	0
Constipation	19 (27%)	0
ALT increased	16 (23%)	0
Platelet count decreased	15 (21%)	3 (4%)
Hyponatraemia	14 (20%)	2 (3%)
AST increased	13 (18%)	2 (3%)
Myalgia	13 (18%)	0

- There were no reports of treatment-related death or interstitial lung disease (ILD).

Preliminary Efficacy

EGFRmut NSCLC

- Among 20 patients with EGFRmut NSCLC (Figure 2), the best objective response rate (ORR) and disease control rate (DCR) were 40% (8/20) and 85% (17/20), respectively. In the D1/D8 Q3W dose groups, the ORR and DCR were 71% (5/7) and 86% (6/7), respectively.

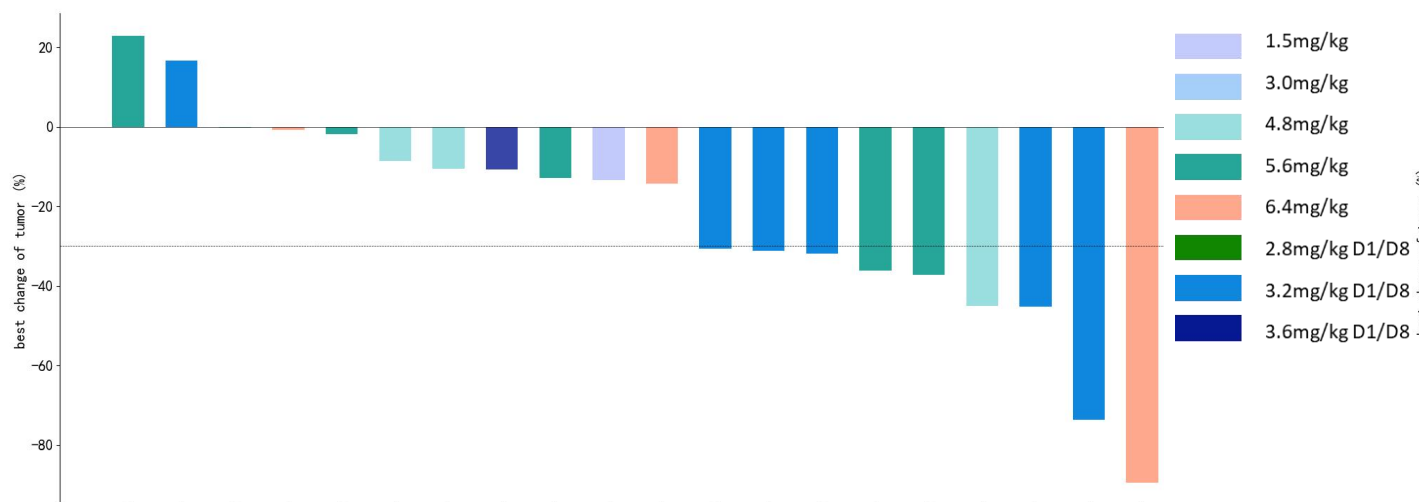


Figure 2. Waterfall Plot of EGFRmut NSCLC

c-MET Protein Expression 2+/3+ ≥ 50%

- Among 20 patients with cMET 2+/3+ ≥ 50% (Figure 3) solid tumors, the ORR and DCR were 40% (8/20) and 95% (19/20), respectively. In the D1/D8 Q3W dose groups, the ORR and DCR were 83% (5/6) and 100% (6/6), respectively.

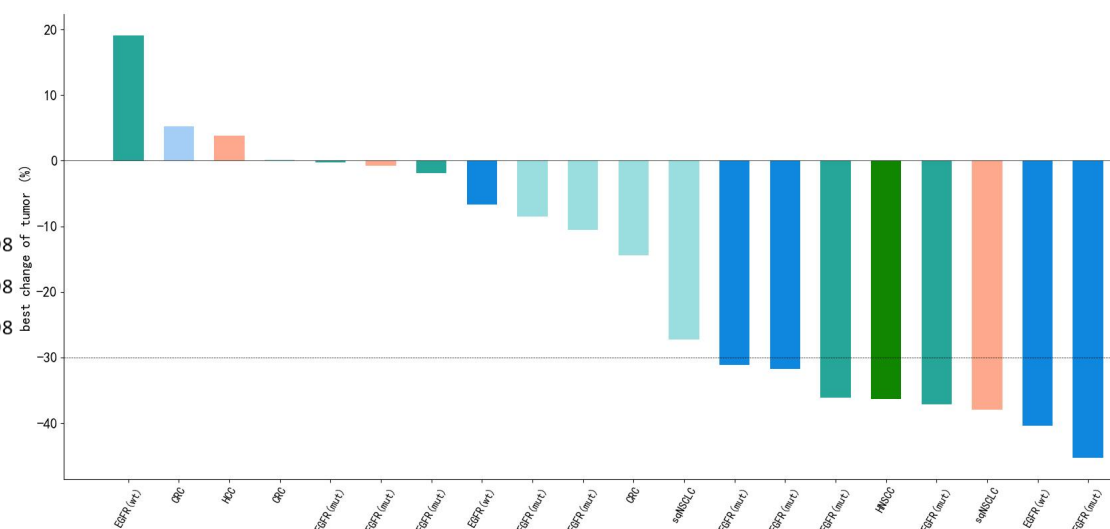


Figure 3. Waterfall Plot of cMET 2+/3+ ≥ 50% Solid Tumor

Swimming Plot and Summary

- ALK202 demonstrated a manageable safety profile and promising antitumor activity in the higher dose group (5.6 & 6.4mg/kg Q3W and 2.8 & 3.2 mg/kg D1/D8 Q3W), particularly in patients with EGFR-mutant NSCLC and c-MET positive (2+/3+ $\geq 50\%$) solid tumors, warranting further investigation at these effective dose levels.

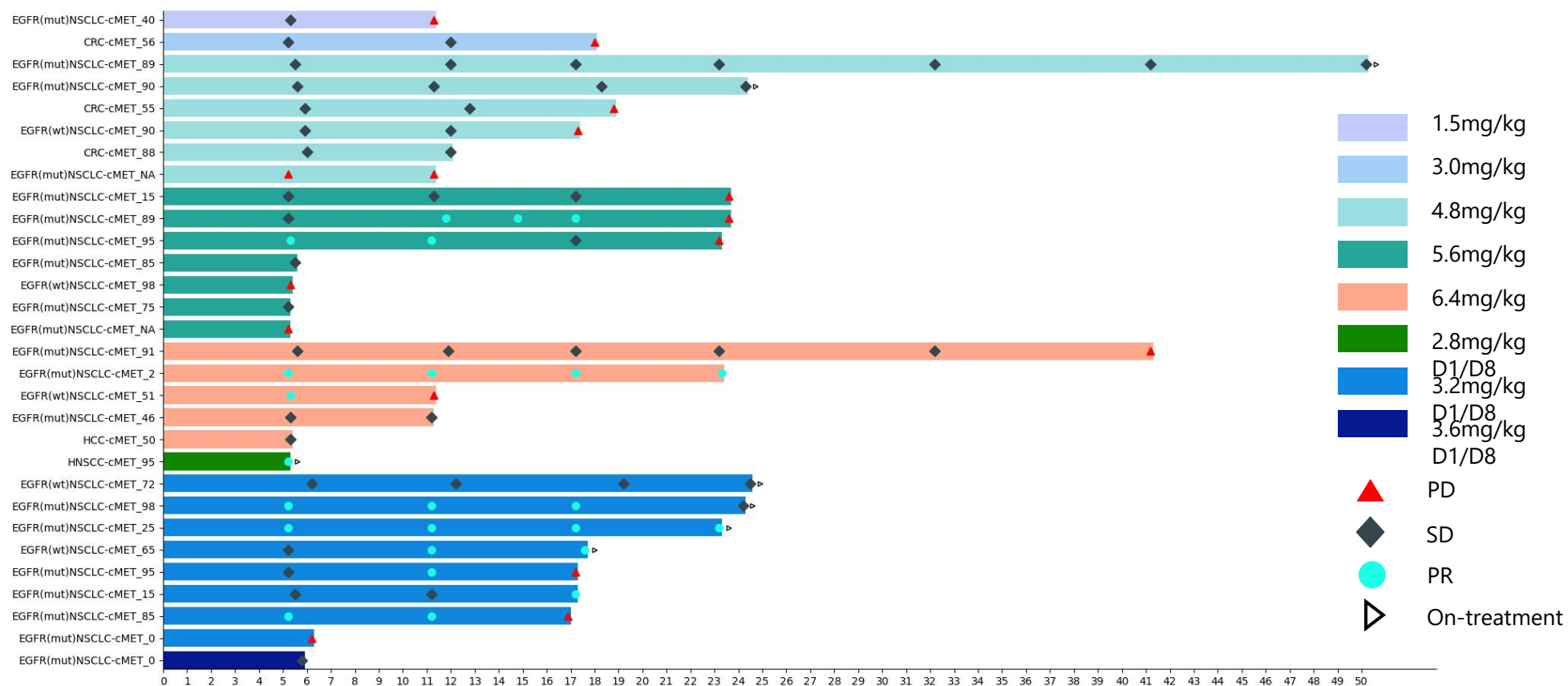
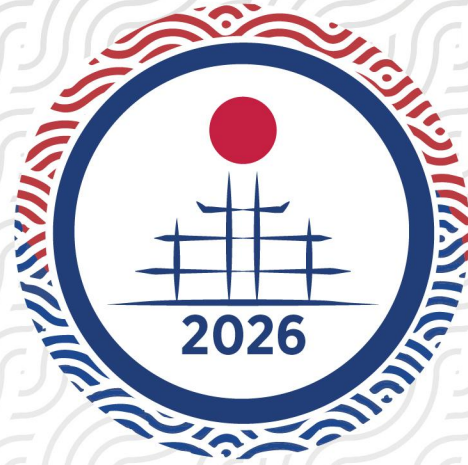


Figure 4. Swimming Plot of EGFRmut NSCLC or c-MET 2+/3+ $\geq 50\%$ Solid Tumor



Thank You.