

First-line BAT8008 (TROP2-ADC) plus BAT1308 (anti-PD-1) for advanced NSCLC: Results from a multicenter phase 2 study

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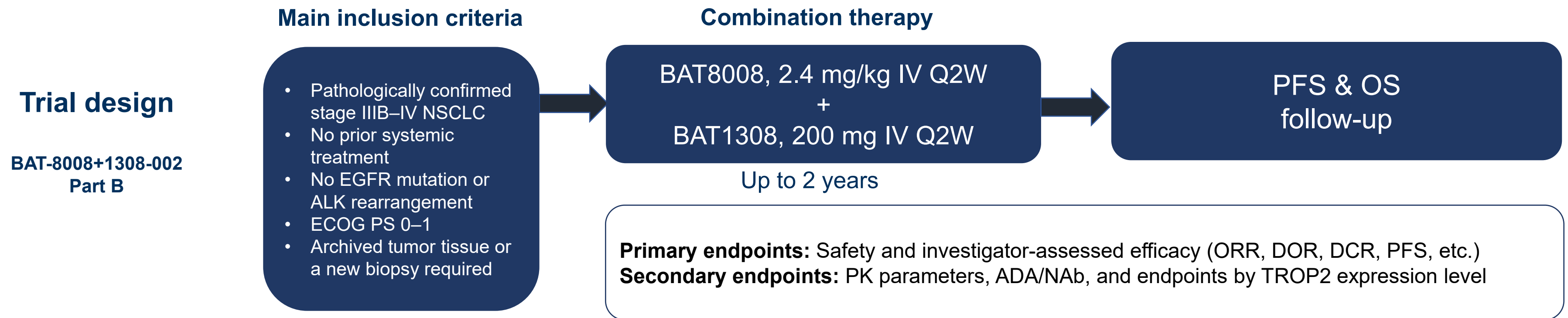
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DECLARATION OF INTERESTS

The authors declare no conflict of interest.

Background & Trial Design

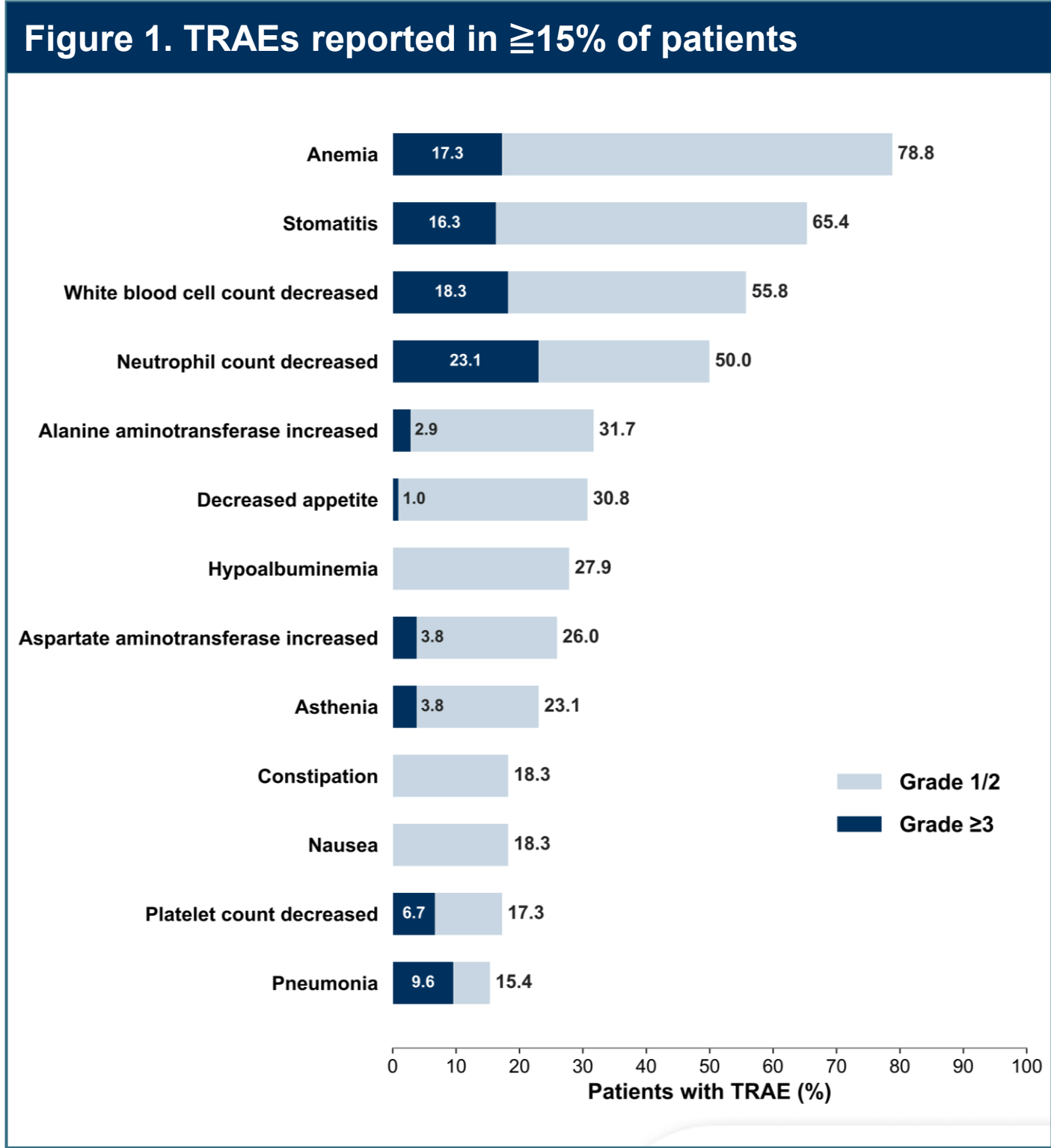
- First-line treatment for advanced NSCLC without targetable genomic alterations is based mainly on immunotherapy alone or combined with chemotherapy, but further improvement in outcomes is needed. TROP2-targeted ADCs may enhance PD-1/L1 blockade through cytotoxicity and immune activation.
- **BAT8008, a TROP2-directed ADC with an exatecan payload (DAR ~6), combined with BAT1308, an anti-PD-1 antibody**, has shown manageable safety and encouraging preliminary antitumor activity across explored dose levels in previously treated NSCLC.



Baseline Characteristics & Safety

- 104 patients recruited in China, and no new safety signals were observed.
- Anemia and stomatitis were the most common TRAEs, with few treatment-related discontinuations.

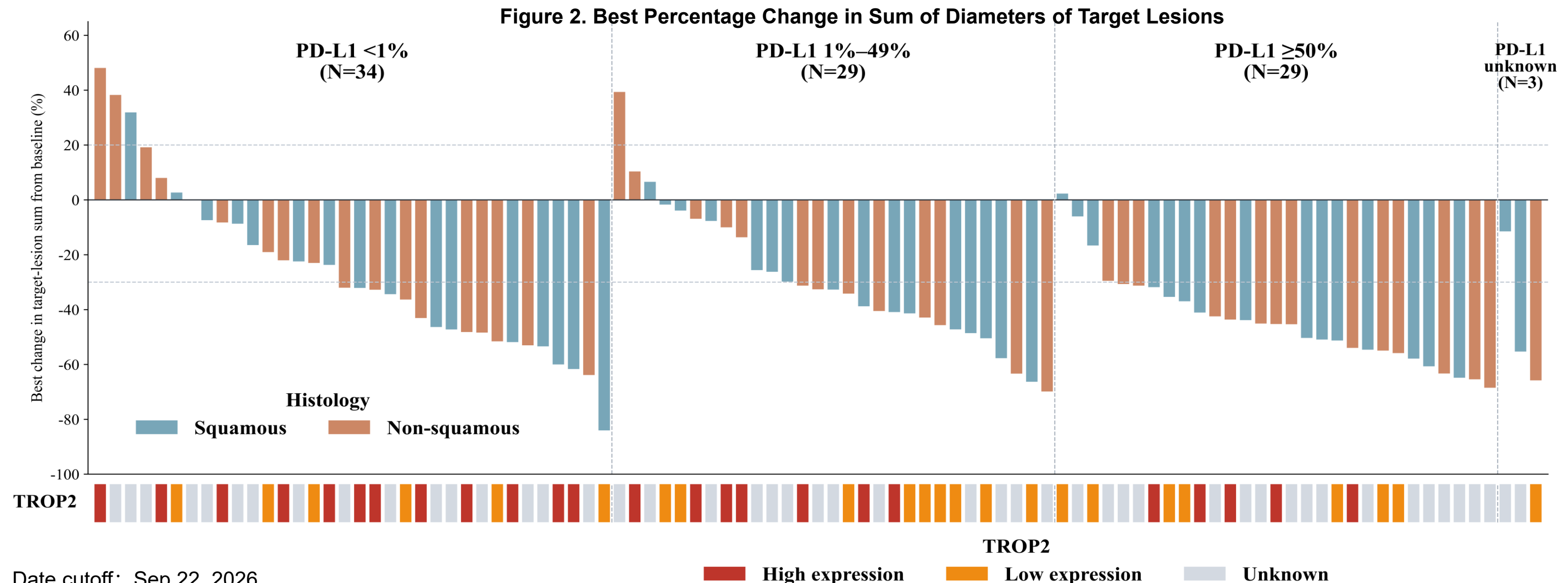
Characteristic	Total (N=104)	Safety summary	Total (N=104)
Age		TEAEs, n (%)	104 (100.0)
Median (range), years	63.5 (39, 76)	Treatment-related	104 (100.0)
Histology		Grade ≥3 TEAEs, n (%)	69 (66.3)
Squamous cell carcinoma	55 (52.9%)	Treatment-related	63 (60.6)
Non-squamous cell carcinoma	49 (47.1%)	Serious TEAEs, n (%)	51 (49.0)
PD-L1 TPS		Treatment-related	41 (39.4)
≥50%	32 (30.8%)	TEAEs leading to discontinuation of any study drug, n (%)	6 (5.8)
1%–49%	30 (28.8%)	Treatment-related	6 (5.8)
<1%	38 (36.5%)	Leading to discontinuation of BAT8008	4 (3.8)
Not tested	4 (3.8%)	Leading to discontinuation of BAT1308	4 (3.8)
ECOG score		TRAEs associated with death, n (%) ^{2*}	1 (1.0)
1	92 (88.5%)		
TROP2 score ^{1*}			
High expression	27 (26.0%)		
Low expression	24 (23.1%)		
Not tested	53 (51.0%)		
Clinical stage			
IV	79 (76.0%)		



Date cutoff: Sep 22, 2026 1* TROP2 score high expression: H-score≥200 2* The only TRAE leading to death was cerebral infarction
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Efficacy

- At a median follow-up of 8.9 months (range, 7.9–9.5), the overall ORR was 61.2%, with higher response rates observed with increasing PD-L1 expression: 47.2% in TPS <1%, 58.6% in TPS 1%–49%, and 83.3% in TPS ≥50%.
- Tumor shrinkage and objective responses were observed across PD-L1 subgroups, histologic subtypes, and TROP2 expression categories.



Date cutoff: Sep 22, 2026

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Efficacy by Histology

- The efficacy spider plot demonstrates that the majority of patients exhibited target lesion shrinkage at their first evaluation, and maintained tumor control across subsequent assessments.
- Patients across different histology types all demonstrated a PFS benefit. Median PFS was 12.42 (6.67-NE) monthes, with 7.72 months in patients with squamous NSCLC and was not reached in patients with non-squamous NSCLC.

Figure 3. Depth and durability of response by histology

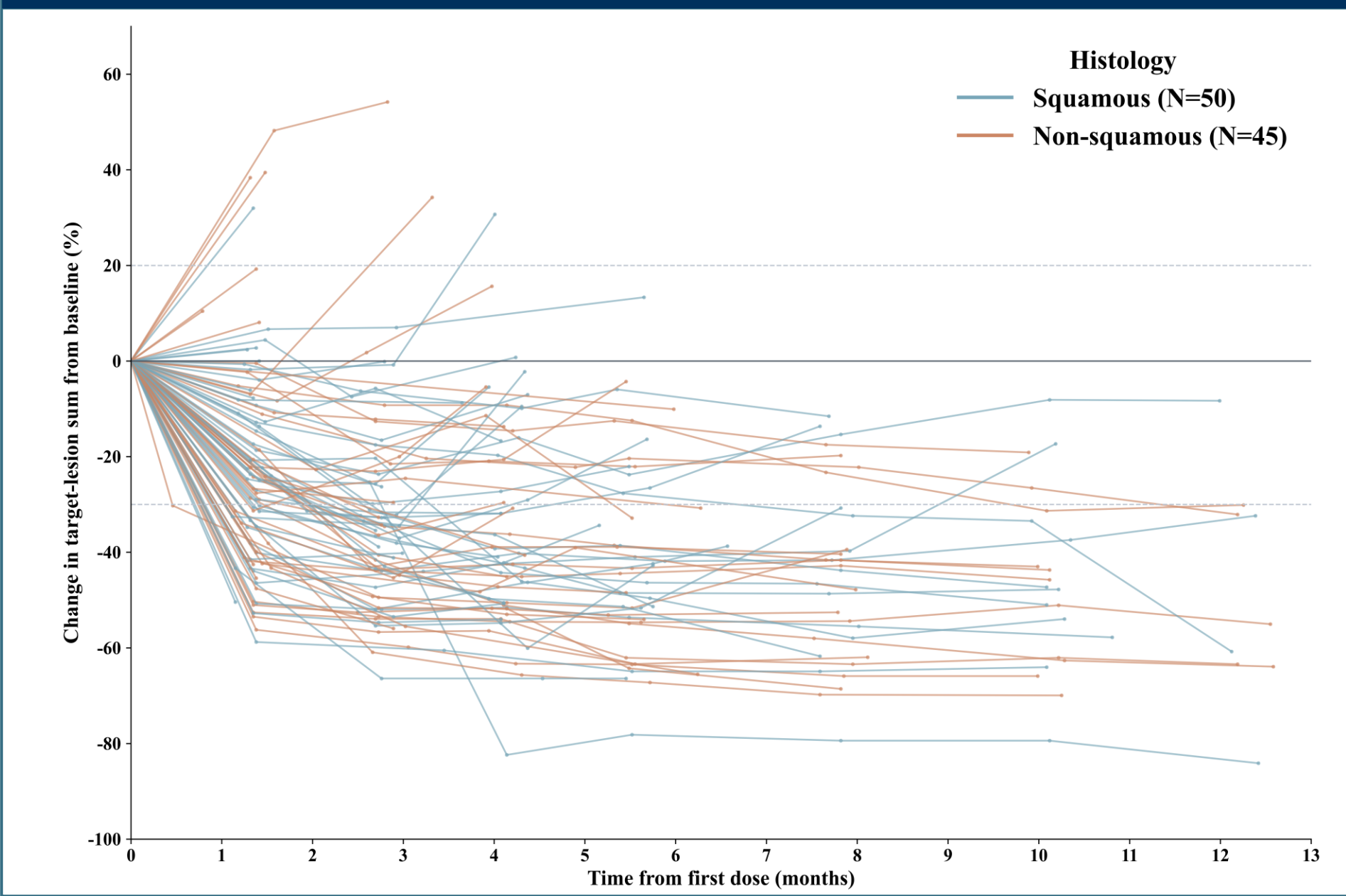
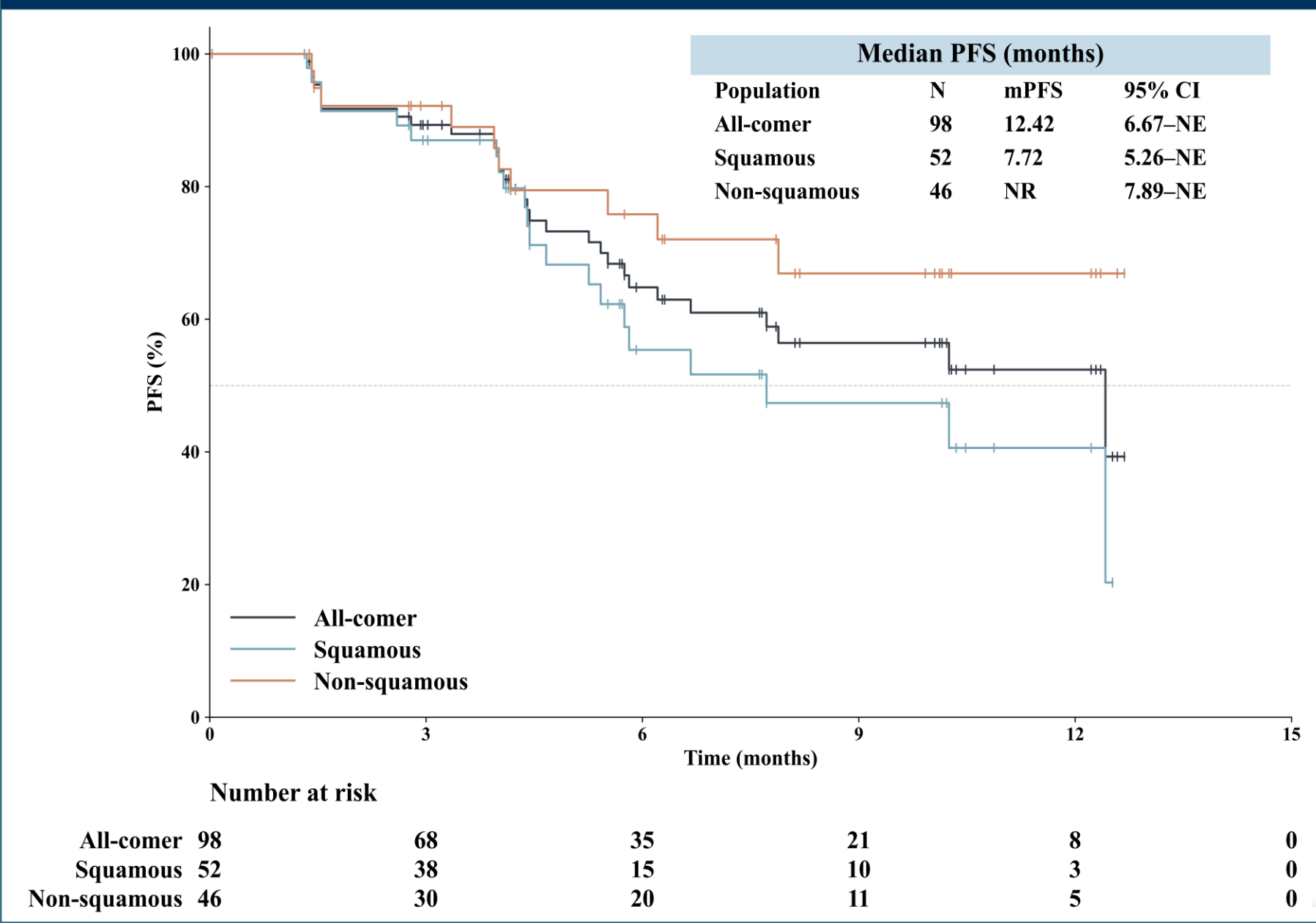


Figure 4. Progression-free survival by histology



Conclusions

- **BAT8008 + BAT1308 demonstrated encouraging and durable antitumor activity as first-line treatment for advanced NSCLC without EGFR or ALK alterations, with particularly notable efficacy in the non-squamous subgroup.**

Overall ORR was **61.2%** with a median PFS of **12.42 months** (95% CI, 6.67–NE); in non-squamous NSCLC, ORR was **65.2%** and median PFS was **not reached** (95% CI, 7.89–NE).

- **The combination showed a manageable safety profile, consistent with the known safety profiles of the individual agents, with no new safety signals identified.**
- **These findings support further clinical development of BAT8008 + BAT1308 as a potential first-line treatment option for patients with advanced NSCLC without actionable genomic alterations.**

Acknowledgements

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Thank you to all participating sites.

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