Abstract 3024

BAT8008, a TROP-2 antibody-drug conjugate (ADC), in patients with advanced solid tumor: Results from a phase 1 study.

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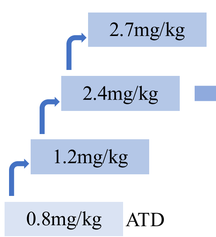
Background

- TROP-2 is a cell surface glycoprotein that is frequently overexpressed in multiple carcinomas
- BAT8008 is a novel Trop2-targered antibody-drug conjugate (ADC) composed of a fully-humanized anti-Trop2 monoclonal antibody covalently linked to topoisomerase I inhibitor payload (Exatecan) via a cleavable maleimide tetrapeptide-based cleavable linker
- Preclinical studies of BAT8008 showed a favorable safety profile and potent antitumor activity.

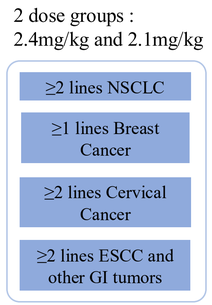
Methods

- This is a first-in-human, dose-escalation and expansion study in patients with advanced/metastatic solid tumors
- Patients are not selected for Trop2 expression except for some certain GI tumor types. The association of trop2 expression level and antitumor response will be assessed.

Part 1- Dose Escalation



Part 2- Dose Expansion



- BAT8008 IV, Q2W
- First cycle is 21d for safety observation
- The dose escalation was design as accelerated titration plus i3+3

Results

Baseline Characteristics

- As of April 20, 2025, 194 patients (pts) were enrolled with doses ranging from 0.8 to 2.7mg/kg.
- Baseline characteristics are included in **Table 1**.

Table 1. Baseline Characteristics

	0.8mg/kg (n=1)	1.2mg/kg (n=3)	2.1mg/kg (n=26)	2.4mg/kg (n= 158)	2.7mg/kg (n=6)	Total (n=194)
Age(Median)	46	49(46-53)	60(34-73)	57(25-78)	61(45-77)	57(25-78)
Male/Female	0/1	1/2	6/20	64/94	2/4	73/121
ECOG 0/1	0/1	0/3	10/16	29/118	0/6	31/163
Tumor type, n(%)						
NSCLC		1	19	44	1	65
Her2- Breast Cancer		1		27	3	31
Cervical Cancer（CC）			7	27		34
Esophageal Cancer（ESCC）				23		23
Other Cancers	1	1		37	2	41
Prior lines of systemic therapy (1-2/3+)	0/1	1/2	7/19	73/85	1/5	82/112

Safety

- 2 out of 6 pts in 2.7mg/kg group had dose limiting toxicity (1 with G3 increased lipase, 1 with G4 thrombocytopenia and G4 febrile neutropenia). The maximum tolerated dose was 2.4mg/kg.
- No obvious ILD, ocular toxicity, or infusion reactions observed.
- The most common treatment-related adverse events (TRAEs) were included in **Table 2.**

Table 2. Summary of TRAEs in ≥20% patients

TRAEs in ≥20% patients	Total (n=194)		2.4mg/kg (n=158)	
	All Grade	≥3 Grade	All Grade	≥3 Grade
Anemia	79.3%	15.0%	79.1%	15.8%
White blood cell count decreased	57.2%	14.9%	61.4%	17.7%
Stomatitis	54.1%	17.5%	57.6%	19.0%
Nausea	51.5%	1.5%	51.9%	1.9%
Neutrophil count decreased	49.0%	18.0%	53.2%	20.3%
Platelet count decreased	32.5%	8.2%	34.2%	9.5%
Vomiting	30.9%	1.5%	32.3%	1.9%
Fatigue	29.9.%	2.6%	33.5%	3.2%
Body weight loss	29.9%	1.0%	32.3%	1.3%
Lymphocyte count decreased	27.8%	5.2%	29.7%	6.3%
Constipation	25.8%	0%	25.3%	0%

Efficacy in 2.4mg/kg Expansion Cohort

- All patients had received at least one line of systemic chemotherapy. Median prior lines of Tx were 2(range, 1-7).
- The reported NSCLC cohort is all driver gene wild-type non-squamous NSCLC.
- The reported Her2- BC cohort includes TNBC and HR+ BC.
- Objective responses were also observed in other solid tumor types.

Table 3. Efficacy in 2.4mg/kg expansion cohort

Tumor Type	CC	ESCC	Her2- BC	NSCLC
n	26	19	26	21
CR	1	1	0	0
PR	8	2	10	5
ORR, %	34.6	15.8	38.5	23.8
DCR, %	73.0	73.7	80.8	95.2
PFS, months (95% CI)	7.0 (6.3-7.7)	4.2 (3.6-4.7)	7.9 (4.9-10.8)	9.4 (6.1-12.7)

Figure 2. Best percent change of target lesion

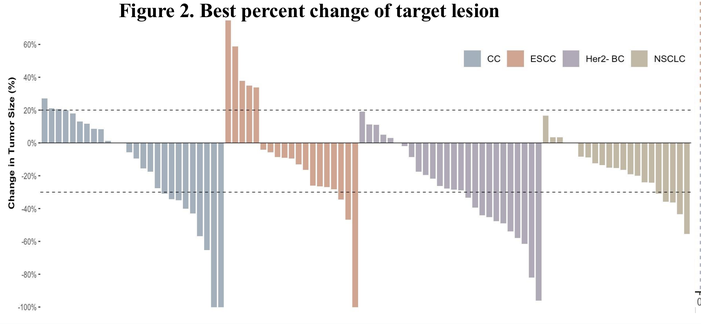
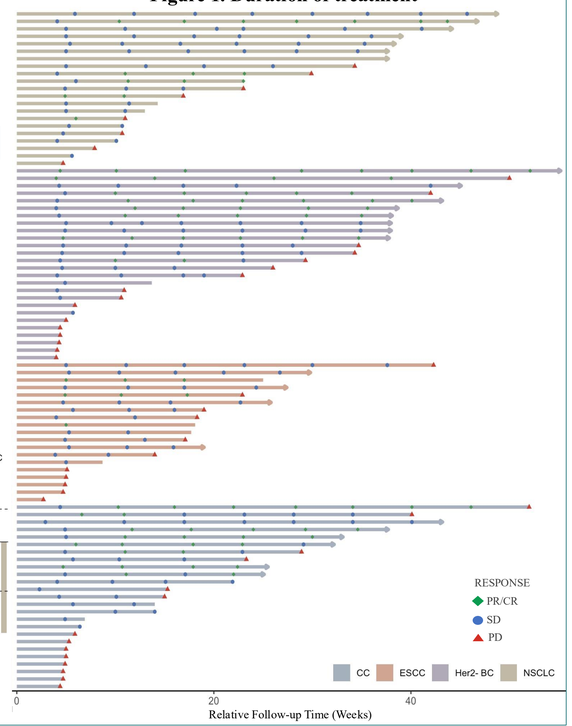


Figure 1. Duration of treatment



Conclusion

- BAT8008 was well tolerated and all AEs were manageable.
- Promising clinical efficacy was observed in pretreated Her2- BC NSCLC ESCC and CC patients at 2.4mg/kg dose level. Expansion study is ongoing at doses of 2.1mg/kg and 2.4mg/kg to evaluate the efficacy and safety of BAT8008 in several types of tumors.
- The exploratory study of BAT8008 in combination with BAT1308 (PD-1 monoclonal antibody) is also underway in patients with ≥1st line various solid tumors.

Acknowledgement

- This study is sponsored by Bio-Thera Solutions, Ltd