2026 ASCO ANNUAL MEETING

BAT8008, a TROP-2 antibody-drug conjugate (ADC), in patients with recurrent or metastatic cervical cancer: A cohort from a phase 1 study

Erwei Song[1] , Jianli Zhao[1], Wenjuan Chen[2], Mingjun Zhang[3], Yongsheng Li[4], Yanhong Zhuo[5], Zhengbo Song[6], Qing Wen[7], Meili Sun[7], Hongrui Niu[8], Jinfeng Ma[9], Xiumin Li[10], Hong Wang[11], Jin Yang[12], Tienan Yi[13], Zhiguo Luo[14], Hao Wang[15], Shengfeng Li[15]

[1]Sun Yat-sen Memorial Hospital, Sun Yat-sen University, Guangzhou, China; [2]Fujian Medical University Cancer Hospital, Fuzhou, China; [3]The Second Affiliated Hospital of Anhui Medical University, Hefei, China; [4]Chongqing University Cancer Hospital, Chongqing, China; [5]Zhangzhou Hospital, Teaching Hospital of Fujian Medical University, Zhangzhou, China; [6] Zhejiang Cancer Hospital, Hangzhou, China; [7]Jinan Central Hospital, Jinan, China; Department of Oncology, Central hospital affiliated to Shandong First Medical University, Jinan, China; [8]Department of Oncology, The First Affiliated Hospital of Xinxiang Medical University, Xinxiang, China; [9]Shanxi Cancer Hospital, Taiyuan, China; [10]Linyi Cancer Hospital, Linyi, China; [11]The Nanchang Third Hospital, Nanchang, China; [12]
China; [13]Oncology Department, Xiangyang Central Hospital, Xiangyang, China; [14]Department of Clinical Oncology, Taihe Hospital, Hubei University of Medicine, Shiyan, China; [15]Bio-Thera Solutions, Ltd, Guangzhou, China

Declaration of interests

Presenter: Erwei Song, MD

No conflicts of interests to disclose.

Key takeways

- BAT8008 demonstrated promising and durable antitumor activity in patients with r/m cervical cancer;

  Overall cORR was 26.5%, with DCR of 77.9%, mPFS of 6.7 months, and mDoR of 9.0 months.

  The 2.4 mg/kg cohort showed favorable efficacy (cORR 29.3%, mPFS 6.7m, mDoR 9.0m).

- BAT8008 showed an acceptable and manageable safety profile;

  Most TRAEs leading to dose modification were predictable and manageable;

  low discontinuation (2.8%) and no treatment-related deaths.

- BAT8008 is a promising agent that may offer a meaningful therapeutic option for patients with heavily pretreated r/m cervical cancer..

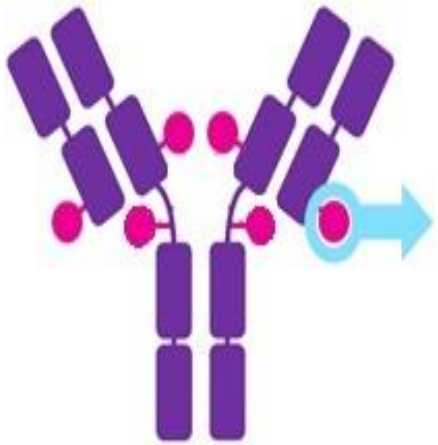
Background

Background

BAT8008 Design

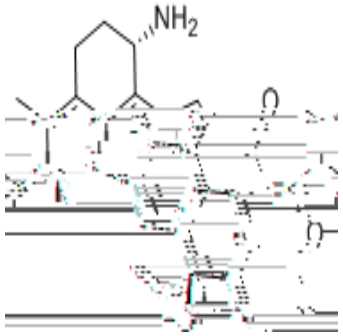
BAT8008 uses a novel ADC platform.

It contains a cleavable linker, Exatecan payload, and a DAR of 6.



DAR ~6

PEG8-vc
cleavable linker



Topoisomerase I inhibitor payload
Exatecan

More stable linker-payload

Payload with higher toxicity than SN38

payload of sacituzumab govitecan 7-Ethyl-10-hydroxy-camptothecin (SN-38)

Study design

Part 1 Dose escalation study in subject with advanced solid tumors

KEY ELIGIBILITY CRITERIA:

Advanced solid tumors refractory to standard therapy (mainly cervical, lung and breast cancer patients)

→

2.7mg/kg

2.4mg/kg

1.2mg/kg

0.8mg/kg

Study endpoints:

- Primary: DLT, AEs, AEs leading to discontinuation or death
- Secondary: PK, PD， immunogenecity

Part 2 Dose optimal/expansion study in subject with specific tumor cohorts

A 8 Cancer

- Nsq-NSCLC
- Her2- Breast Cancer
- Cancer and Other GI Tumors

→

KEY ELIGIBILITY CRITERIA:

Histologically confirmed locally advanced or metastatic cervical cancer;

Prior Lines of systemic therapy 1L

Measurable target lesion (according to RECIST v1.1).

ECOG PS score 0 or 1;

→

BAT8008

2.4mg/kg IV Q2W

or

2.1mg/kg IV Q2W

Until Disease progression, death, or intolerable toxicity

Study endpoints:

- Primary: ORR (according to RECIST v1.1)
- Secondary: PFS, OS, safety profile and PK, PD

DLT: Dose-Limiting Toxicity PK Pharmacokinetics PD Pharmacodynamics

Demographics of Cervical Cancer Cohort

By Apr 17, 2026, 71 r/m cervical cancer patients were enrolled (majority squamous).

Of these, 62% 53.6% had prior immunotherapy.

Baseline Characteristics	All Patients (N=71)	2.1 mg/kg (N=27)	2.4 mg/kg (N=44)
Demographics			
Age, years Median (Range)	53.0 (25.0 77.0)	56.0 (34.0 77.0)	51.0 (25.0 73.0)
Histological Type Sq/ Non-sq, n (%)	47 (66.2%) / 24 (33.8%)	16 (59.3%) / 11 (40.7%)	31 (70.5%) / 13 (29.5%)
Prior Treatment Characteristics			
Prior Lines of Systemic Therapy n (%)	44 (62.0%)	18 (66.7%)	26 (59.1%)
Prior Anti-angiogenic Therapy Yes, n (%)	44 (62.0%)	20 (74.1%)	24 (54.5%)
Prior Immunotherapy Yes, n (%)	38 (53.6%)	15 (55.6%)	23 (52.3%)
Disease Characteristics			
Metastatic Sites: Liver Yes, n (%)	5 (7.0%)	1 (3.7%)	4 (9.1%)
Metastatic Sites: Lung Yes, n (%)	26 (36.6%)	13 (48.1%)	13 (29.5%)
Metastatic Sites: Bone Yes, n (%)	10 (14.1%)	0 (0.0%)	10 (22.7%)

Data cut-off date Apr 17, 2026

Efficacy

By Apr 17, 2026, 68 patients were evaluable (median follow-up 9.4 months).

The 2.4 mg/kg cohort showed better efficacy: cORR 29.3%, mPFS 6.7 months.

Efficacy	2.1 mg/kg N=27	2.4 mg/kg N=41	Overall N=68
CR	1	2	3
PR	6	12	18
ORR, %	25.9 (13.2 44.7)	34.1 (21.6 49.5)	30.9 (21.2 42.6)
cORR, %	22.2 (10.6 40.8)	29.3 (17.6 44.5)	26.5 (17.4 38.0)
DCR, %	81.5 (63.3 91.8)	75.6 (60.7 86.2)	77.9 (66.7 86.2)
mPFS, months	5.4 (3.3 9.0)	6.7 (3.5 11.5)	6.7 (3.6 9.0)
mDoR, months	6.9 (6.2 10.3)	9.0 (4.2 NR)	9.0 (6.2 12.3)
mOS, months	NR (NR NR)	17.8 (13.4 NR)	17.8 (13.4 NR)

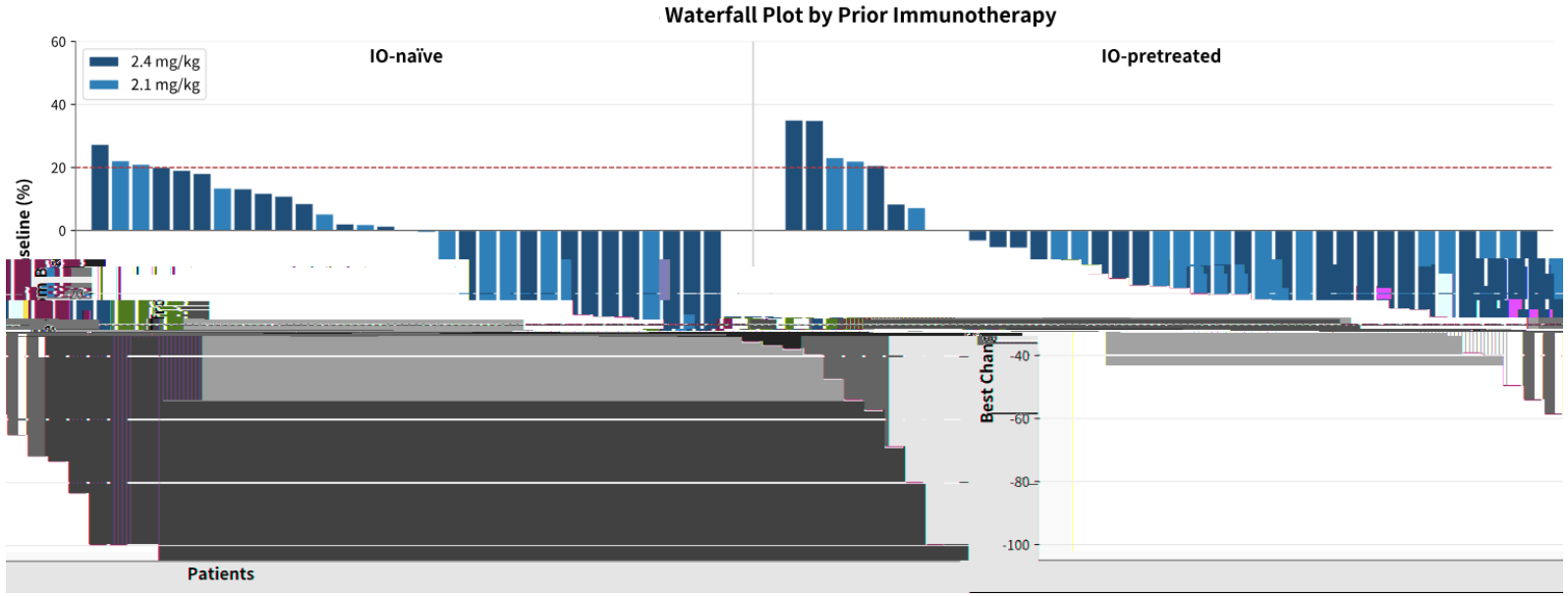
Data cut-off date Apr 17, 2026

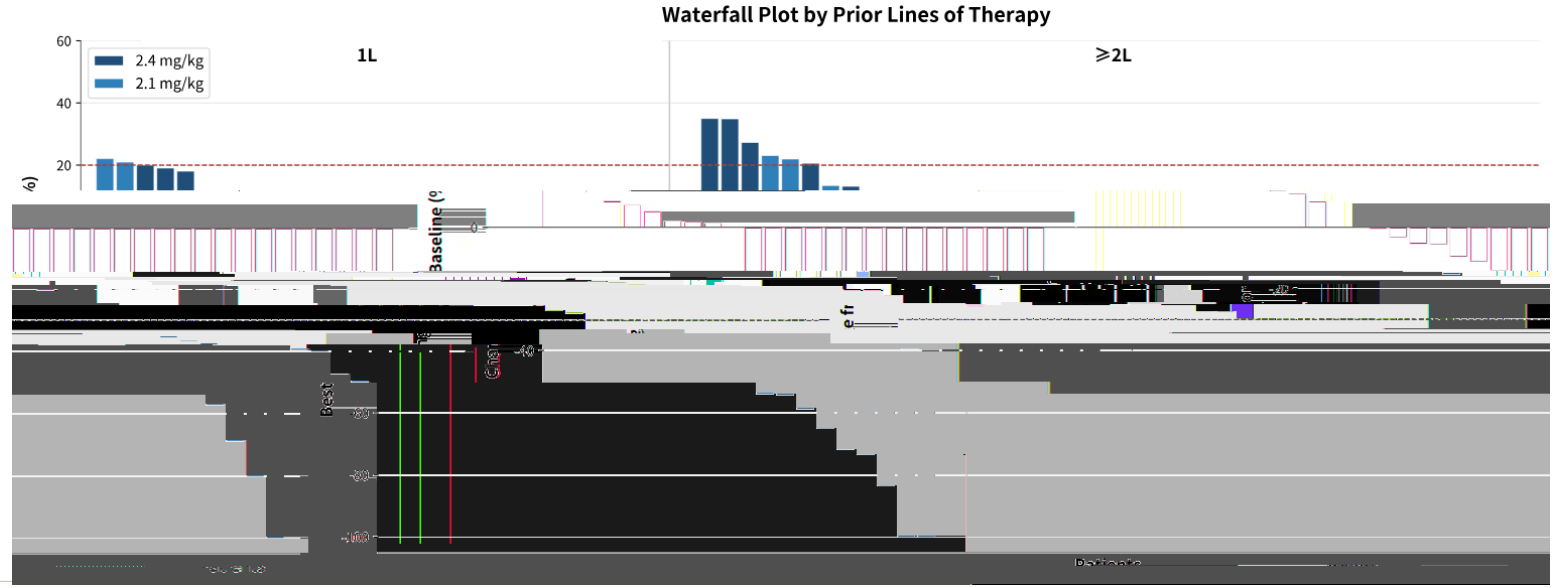
Efficacy

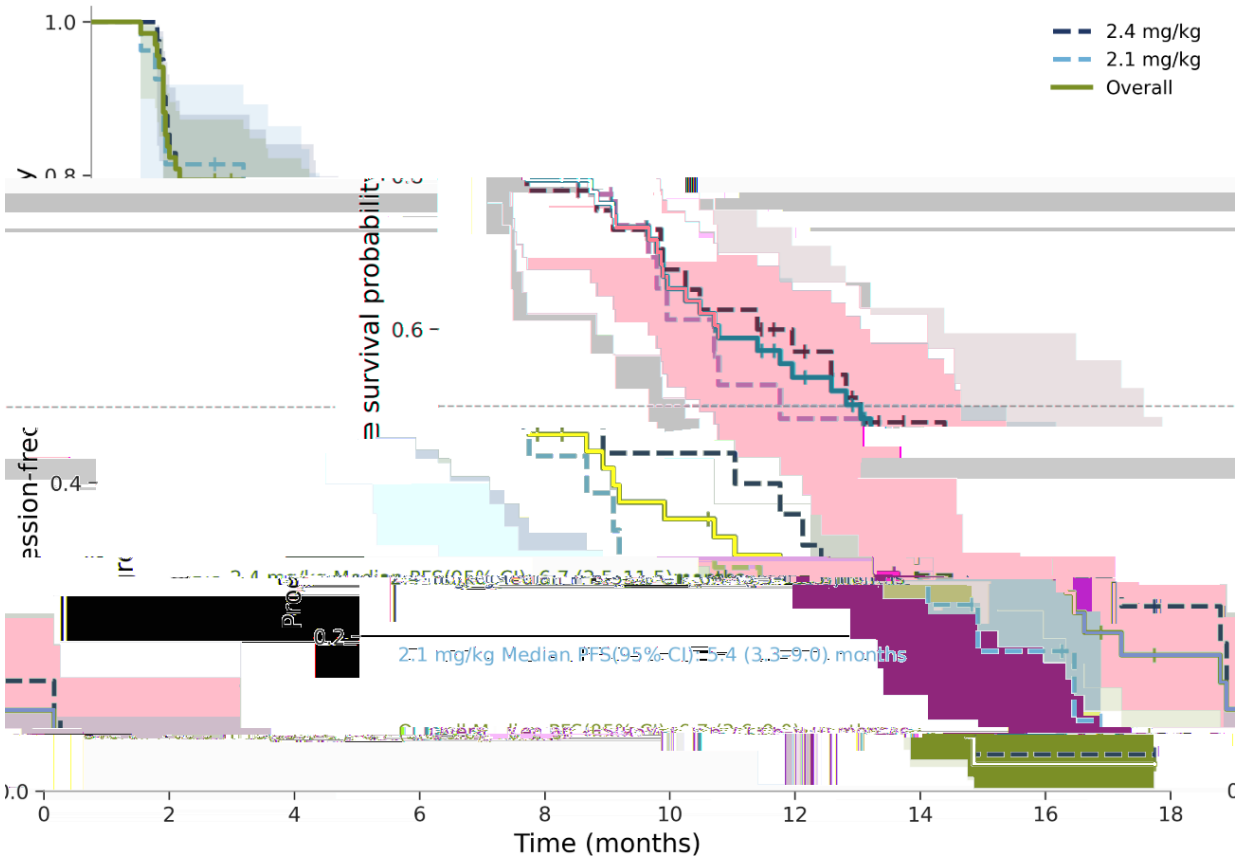
2.4 mg/kg group achieved more robust tumor shrinkage than 2.1 mg/kg.

Efficacy

Responses were independent of prior therapy lines, immunotherapy, or anti-angiogenic treatment.






2.4 mg/kg
2.1 mg/kg
Overall
1.0
0.6
0.4
0.2
0.0
survival probability
ression-free
2.1 mg/kg Median PFS (95% CI) 5·4 (3·3–9·0) months
0
2
4
6
8
10
12
14
16
18
Time (months)

Efficacy

BAT8008: Suggestive of better efficacy vs. later-line standards (across different cohorts)

	BAT8008	TF-ADC: Tisotumab vedotin* innovaTV 301 Phase III	chemotherapy* innovaTV 301 Phase III
Treatment	BAT8008 2.4 mg/kg IV Q2W	Tisotumab vedotin-tftv 2.0 mg/kg IV Q3W	choice chemotherapy
Population	r/m cervical cancer; 59.1% 2 prior systemic line	r/m cervical cancer after 1 2 prior systemic regimens	r/m cervical cancer after 1 2 prior systemic regimens
cORR, % (95% CI)	29.3	17.8	5.2
DCR, % (95% CI)	75.6	75.9	58.2
mPFS, months (95% CI)	6.7 (3.5 11.5)	4.2 (4.0 4.4)	2.9 (2.6 3.1)
mDoR, months (95% CI)	9.0 (4.2 NR)	5.3 (4.2 8.3)	5.7 (2.8 NR)
mOS, months (95% CI)	17.8 (13.4 NR)	11.5 (9.8 14.9)	9.5 (7.9 10.7)

* Vergote I, et al. N Engl J Med. 2024;391(1):44-55.

Safety

TRAEs	2.1 mg/kg (N=27) n (%)	2.4 mg/kg (N=44) n (%)	(N=71) n (%)
Any TRAE	27 (100.0)	42 (95.5)	69 (97.2)
Grade (TRAE	17 (63.0)	26 (59.1)	43 (60.6)
TRAE leading to SAE	12 (44.4)	15 (34.1)	27 (38.0)
TRAE leading to dose interruption	13 (48.1)		

(591)

(48.1)

Safety

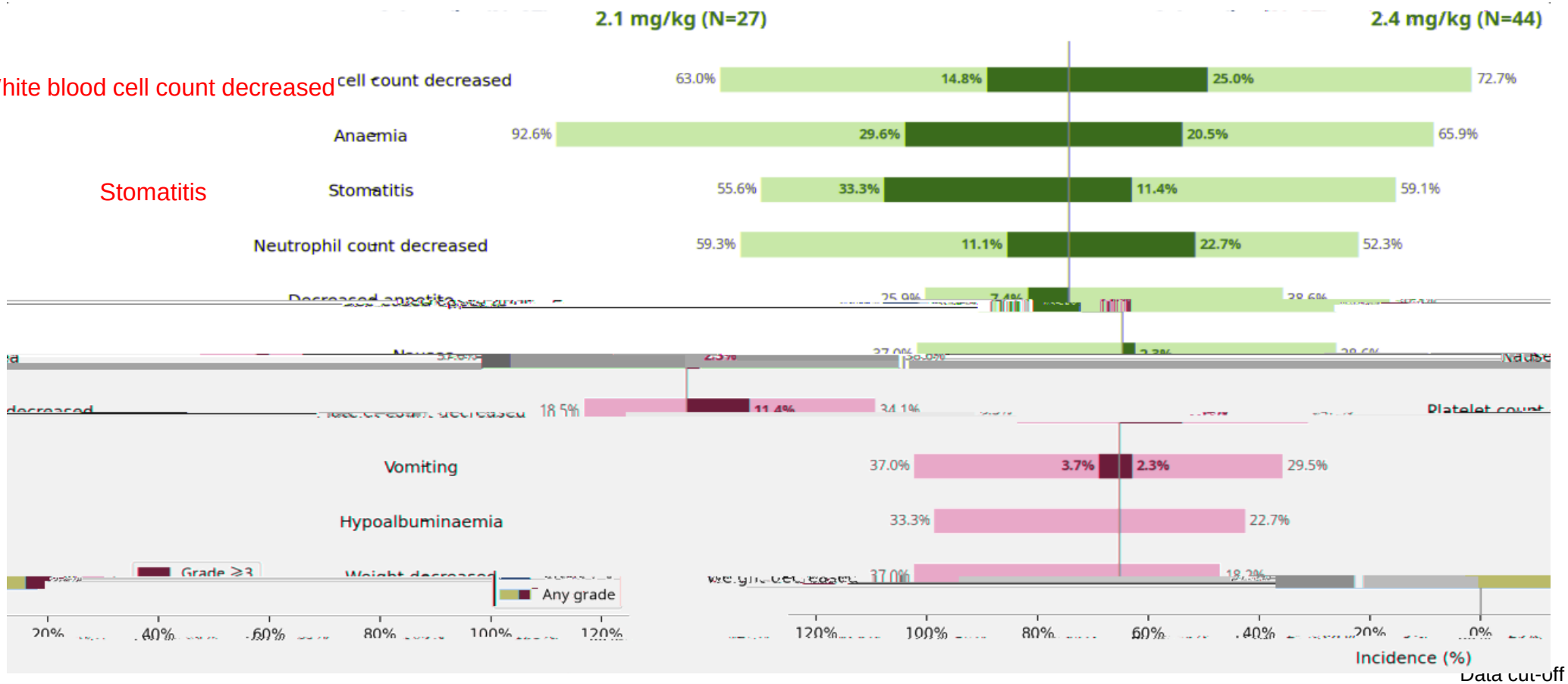
Most common TRAEs: hematological and GI events, mostly low-grade.

≥G3 neutropenia: 11.1%　2.1mg/kg　/ 22.7%　2.4mg/kg　.

Other Grade ≥3 toxicities matched exatecan ADC profile; no unexpected signals.

White blood cell count decreased

Stomatitis



Data cut-off date Apr 17, 2026

Efficacy of Other Cohort

Broad anti-tumor activity across multiple tumors, especially HR+ mBC (ORR 45.5%, mPFS 10.8 m)

Efficacy	TNBC 2.4 mg/kg N=32	HR+ BC 2.4 mg/kg N=44	NSCLC 2.4 mg/kg N=42
CR	0	0	0
PR	11	20	9
ORR, %	34.4	**45.5**	21.4
DCR, %	87.5	81.8	90.5
mPFS, months	6.7 (2.6 9.7)	**10.8** (5.2 14.3)	6.2 (5.3 8.3)

Conclusion

- BAT8008 demonstrated promising and durable antitumor activity in patients with r/m cervical cancer;

  Overall cORR was 26.5%, with DCR of 77.9%, mPFS of 6.7 months, and mDoR of 9.0 months.

  The 2.4 mg/kg cohort showed favorable efficacy (cORR 29.3%, mPFS 6.7m, mDoR 9.0m).

- BAT8008 showed an acceptable and manageable safety profile;

  Most TRAEs leading to dose modification were predictable and manageable;

  low discontinuation (2.8%) and no treatment-related deaths.

- BAT8008 is a promising agent that may offer a meaningful therapeutic option for patients with heavily pretreated r/m cervical cancer..

Acknowledgement

We would like to thank

All patients and their families participating in the study;

All investigators, research personnel, and staff who conducted this trial;

Sponsor: Bio - thera Solution Co., Ltd;

2026 ASCO Congress Organization Committee.