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

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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).

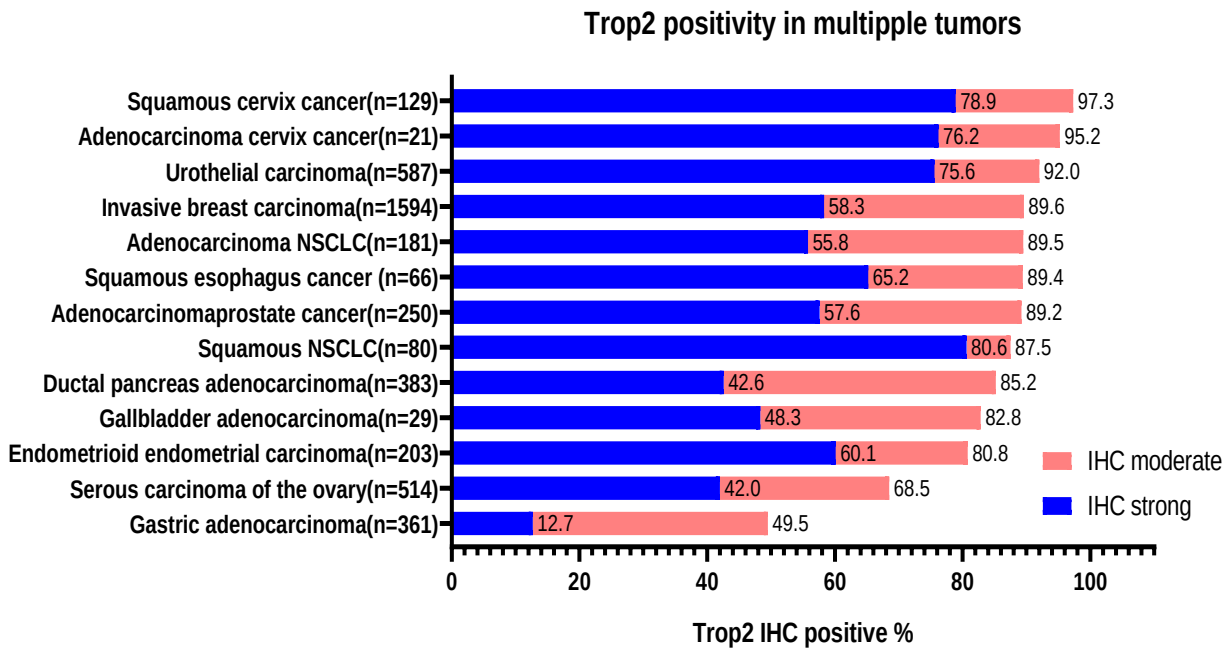
- BAT8008 showed an acceptable and manageable safety profile;
  - Most TRAEs leading to dose modification were predictable and manageable;
  - low discontinuation (2.8%) and no treatment-related deaths.

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

Background

Target Expression

- Trop2 is overexpressed in many solid tumors (e.g., cervical, lung, breast, endometrial) but rarely in normal tissues.
- >95% of cervical cancer patients show Trop-2 expression, much higher than in normal tissues.

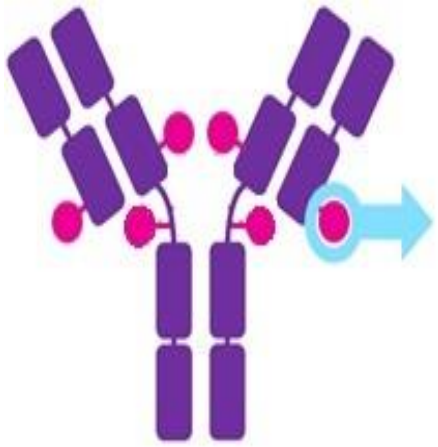


Dum D, et al. *Pathobiology*. 2022;89(4):245-258.

Background

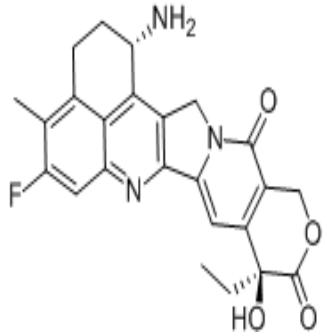
BAT8008 Design

- 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

≥2L Cervical Cancer

≥2L Nsq-NSCLC

≥2L Her2- Breast Cancer

≥2L Esophageal 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% had ≥2 prior lines of therapy and 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 — ≥2L, 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

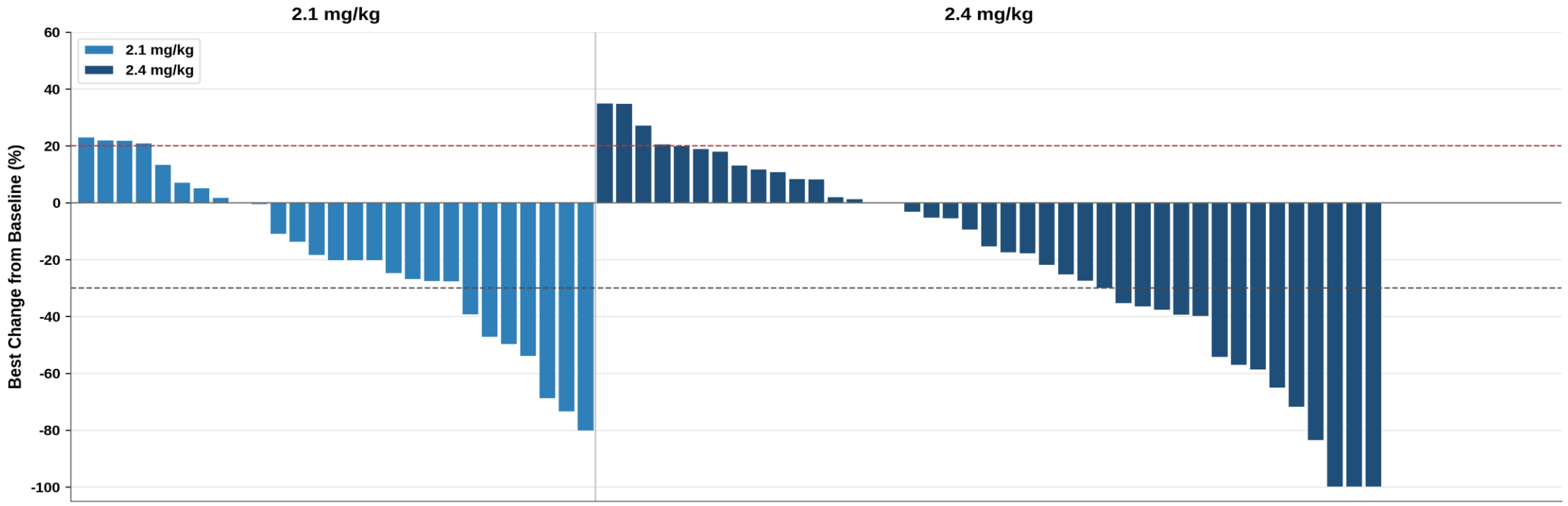
- By Apr 17, 2026, 68 patients were evaluable (median follow-up 9.4 months).
- The 2.4 mg/kg cohort showed better efficacy: cORR 29.3%, mPFS 6.7 months.

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

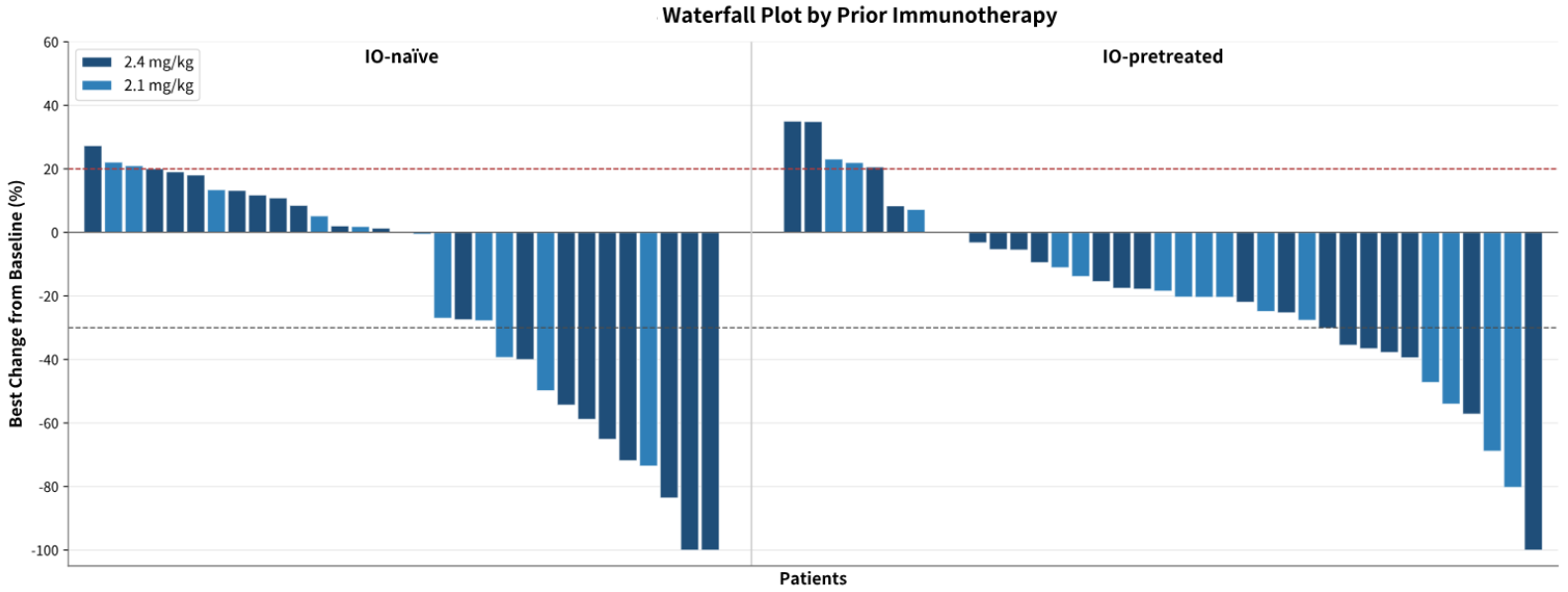
Efficacy

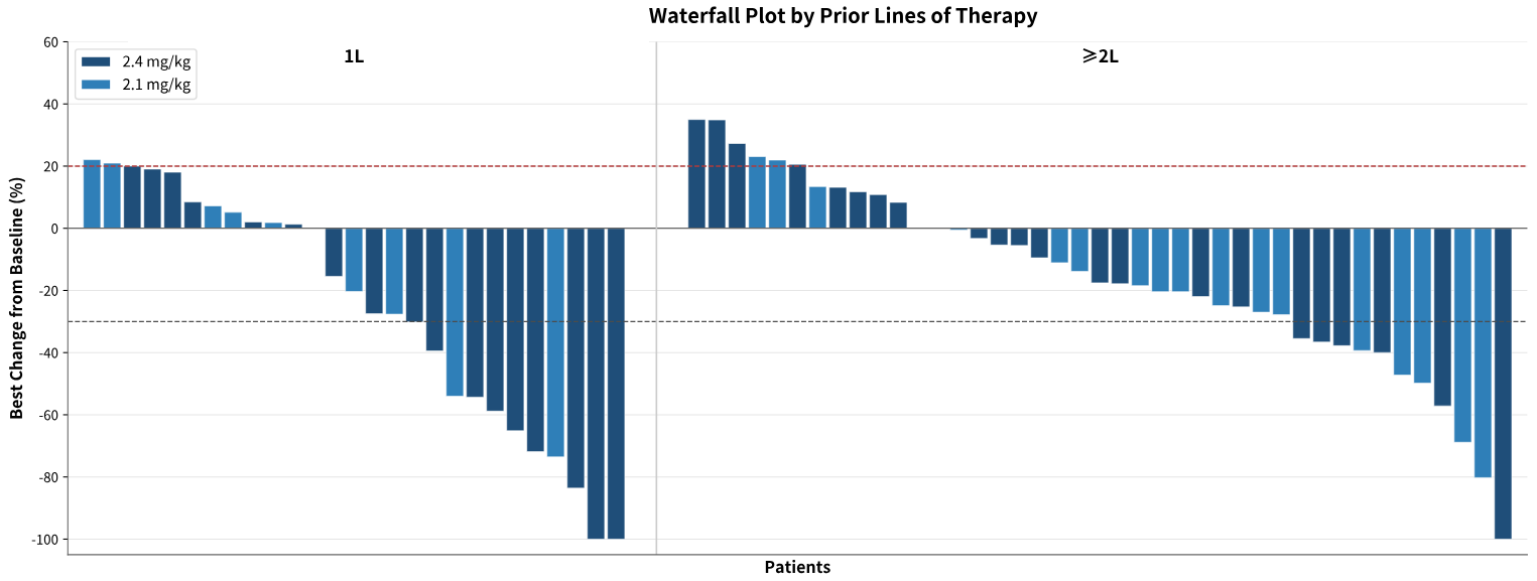
- 2.4 mg/kg group achieved more robust tumor shrinkage than 2.1 mg/kg.



Efficacy

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

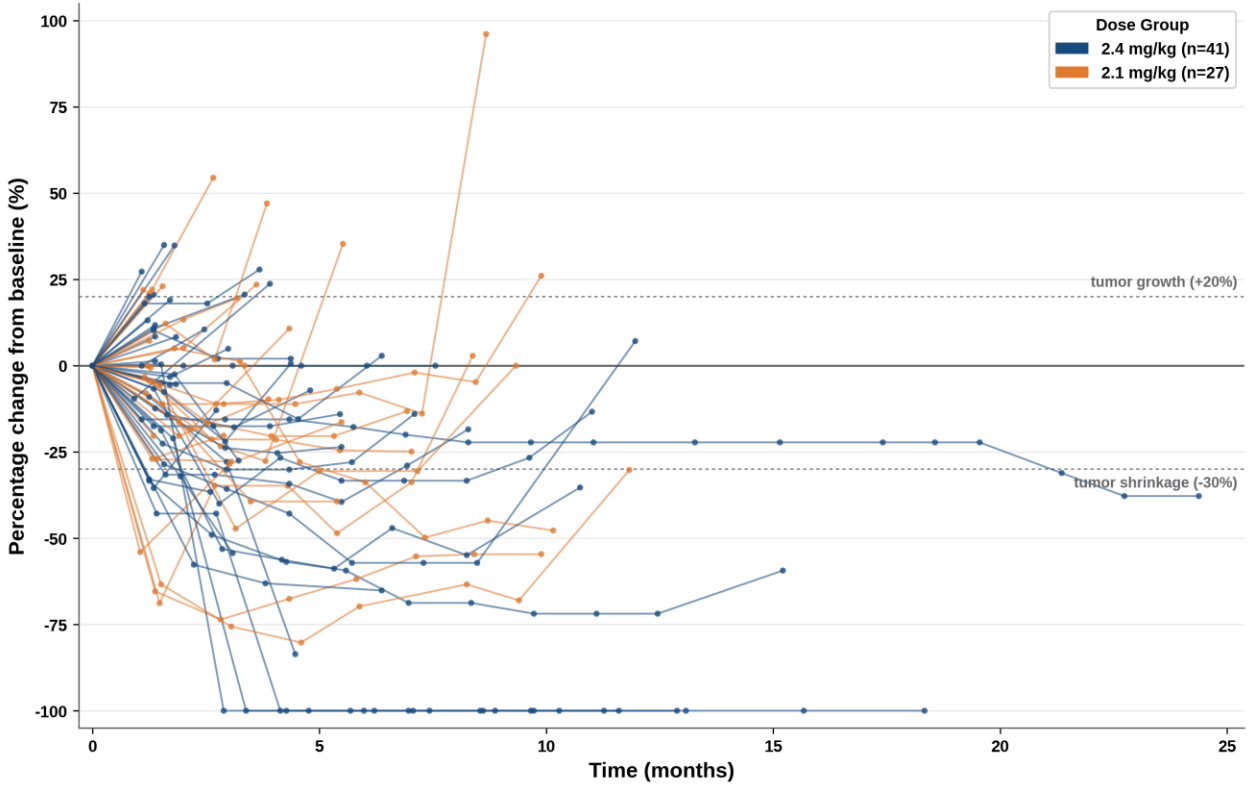




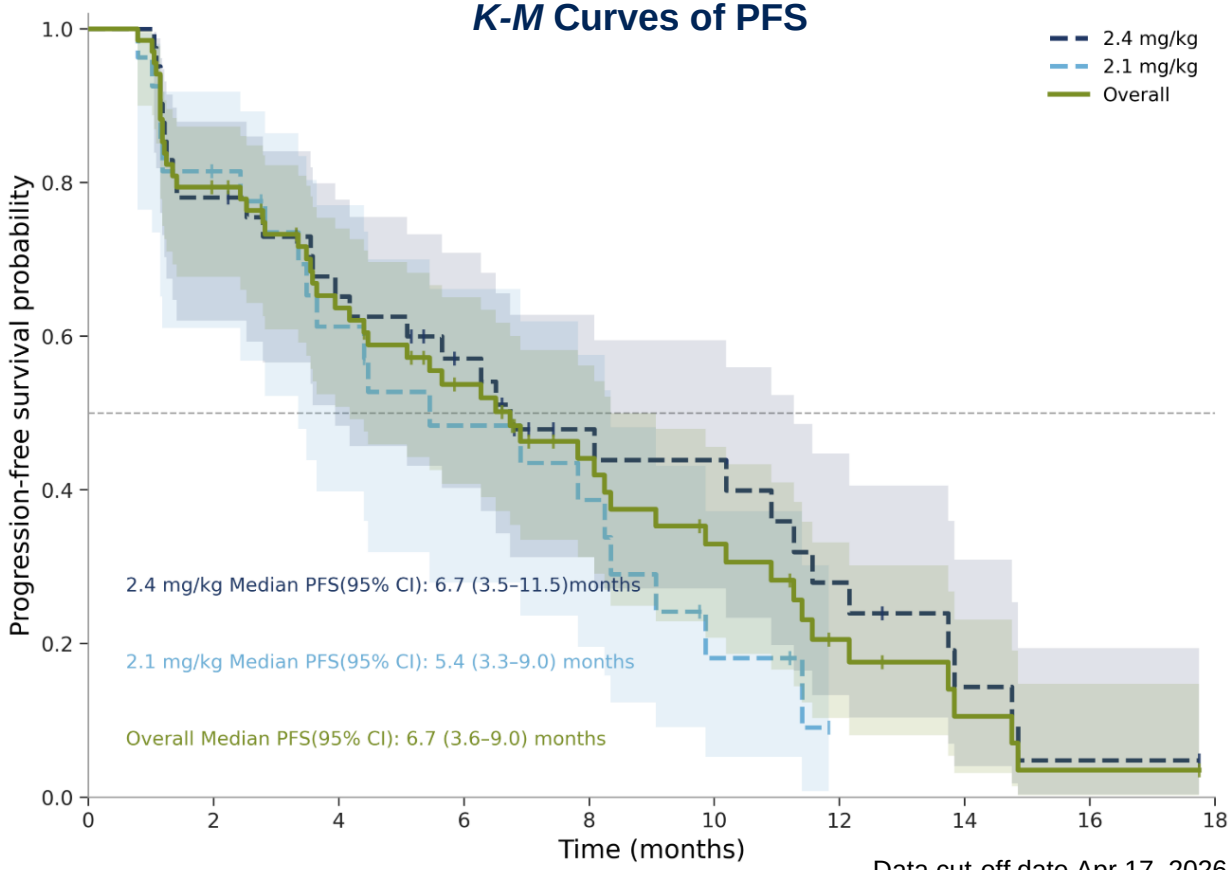
Efficacy

- **Duration of disease control(DoR):** Maximum DoR reached 24m, Overall mDoR was 9.0m.
- **mPFS:** Overall mPFS was 6.7months, with the 2.4 mg/kg dose group achieving a longer mPFS compared to the 2.1 mg/kg group (6.7 vs. 5.4 months).

Spider Plot of Percentage Change from Baseline in Target Lesion



***K-M* Curves of PFS**



Data cut-off date Apr 17, 2026

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	Investigator's 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

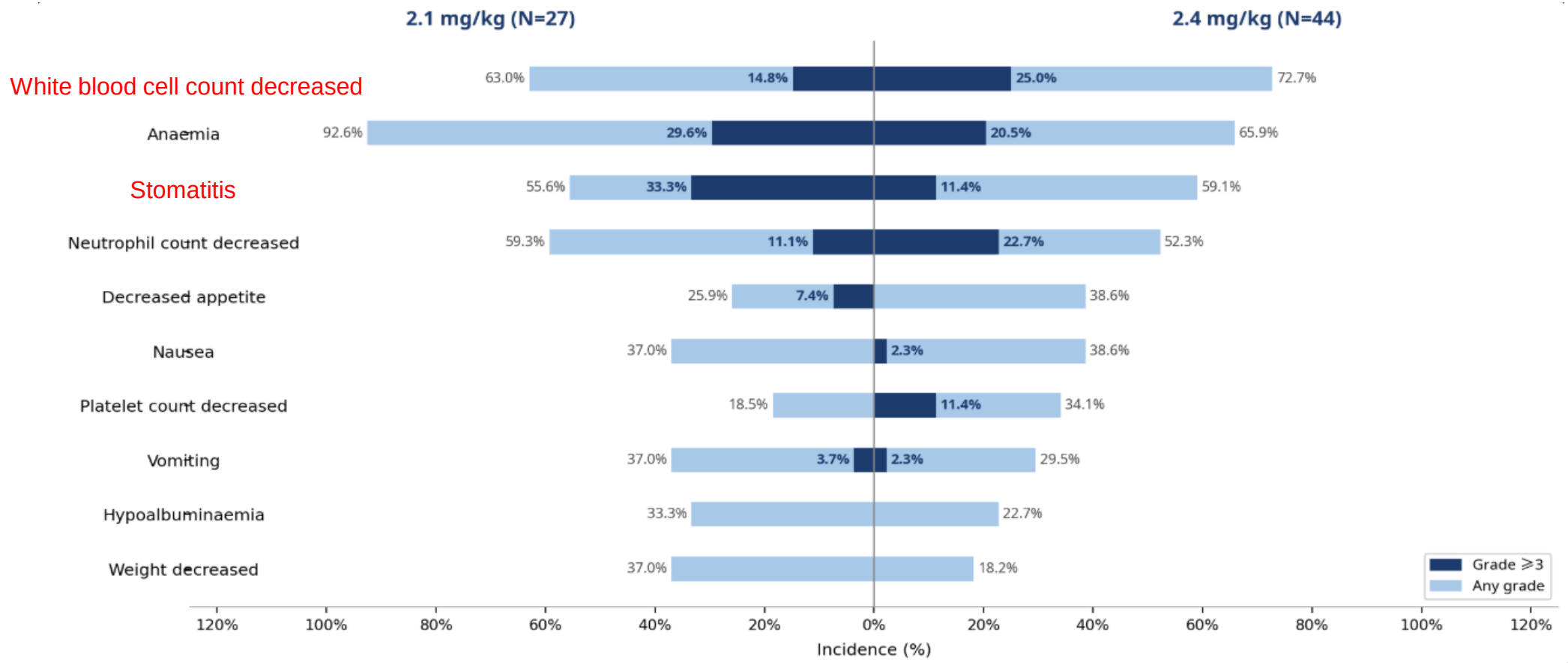
- Overall safety manageable: low discontinuation (2.8%) and no treatment-related deaths.
- Most dose-modifying TRAEs predictable/manageable; acceptable tolerability in both dose cohorts.

TRAEs	2.1 mg/kg (N=27) n (%)	2.4 mg/kg (N=44) n (%)	Overall (N=71) n (%)
Any TRAE	27 (100.0)	42 (95.5)	69 (97.2)
Grade ≥3 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)	26 (59.1)	39 (54.9)
TRAE leading to dose reduction	9 (33.3)	12 (27.3)	21 (29.6)
TRAE leading to treatment discontinuation	0 (0.0)	2 (4.5)	2 (2.8%)
TRAE leading to death	0 (0.0)	0 (0.0)	0 (0.0)

Data cut-off date Apr 17, 2026

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.

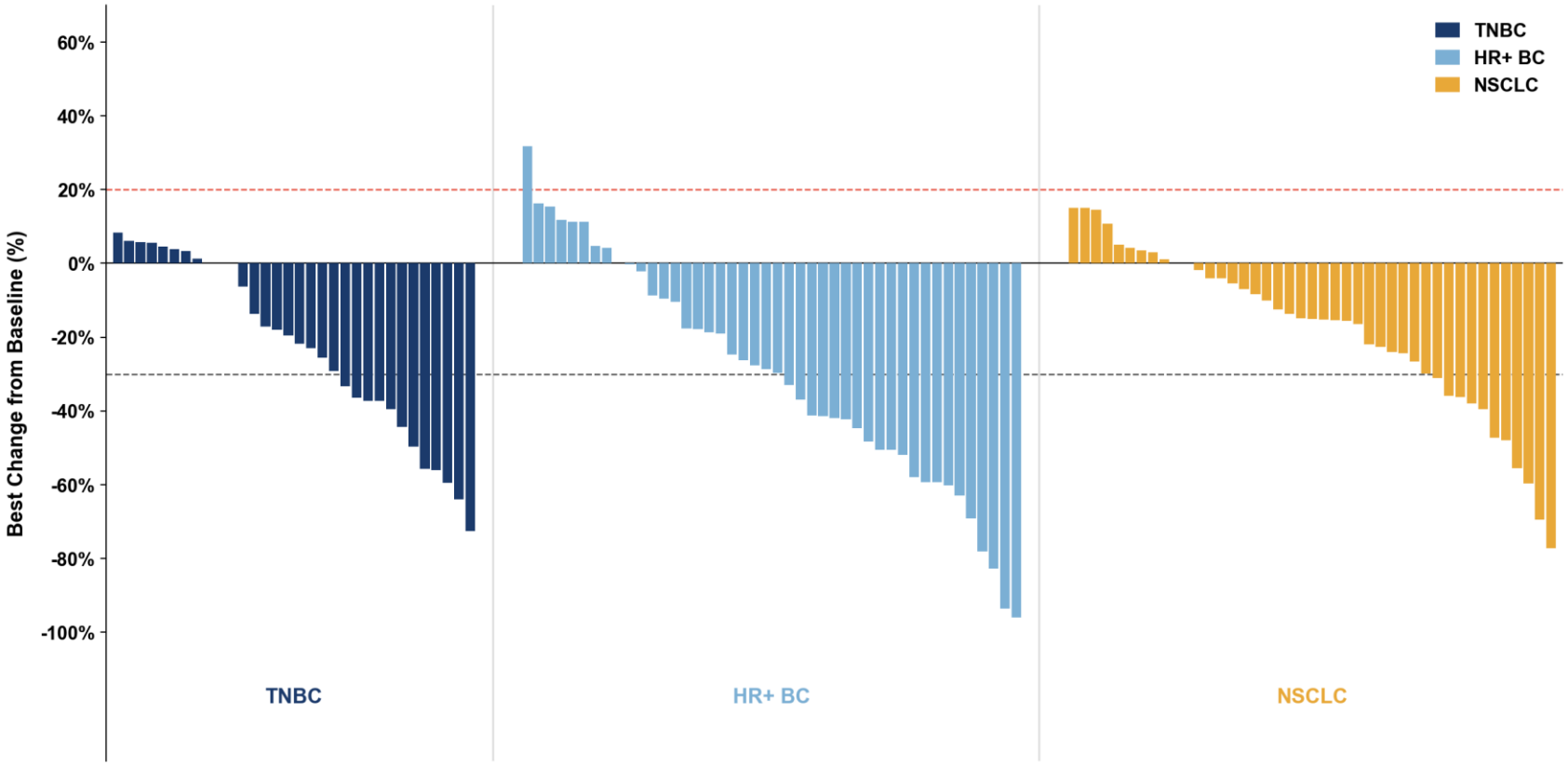


Data cut-off date Apr 17, 2026

Efficacy of Other Cohort

- Broad anti-tumor activity across multiple tumors, especially HR+ mBC (ORR 45.5%, mPFS 10.8 m) and TNBC.
- More robust and durable responses in heavily pretreated patients across different cohorts, supporting its potential as a broad-spectrum ADC.

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)



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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;
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  - 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..

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