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Safety and Efficacy of BAT8006 in combination with BAT1308 in Patients with Advanced Endometrial Cancer

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Background

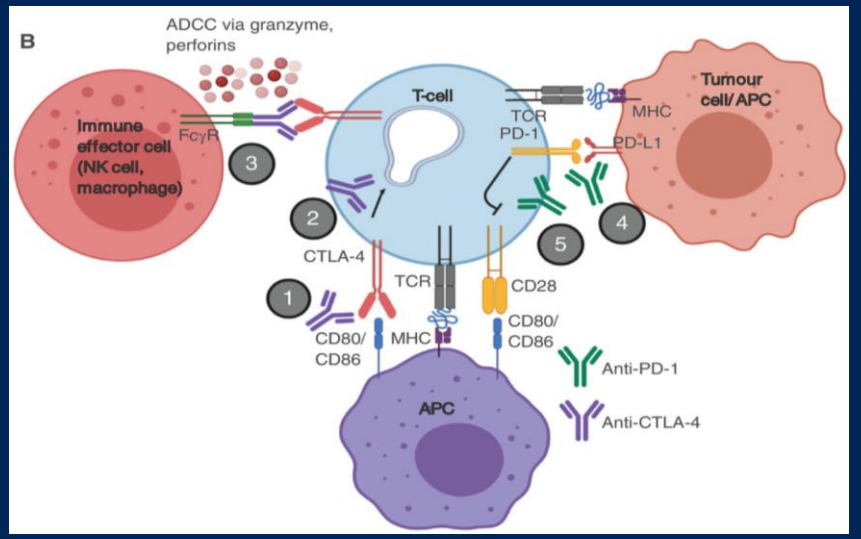
BAT8006 is a folate receptor alpha (FR targeted ADC consisting of three components: a recombinant humanized anti-FR antibody, a cleavable linker, and the small-molecule drug exatecan. The drug-to-antibody ratio (DAR) stands 7~8.

After binding to FR on tumor cells, BAT8006 is internalized to release exatecan, which inhibits DNA topoisomerase I and induces tumor cell apoptosis.

Released exatecan from apoptotic tumor cells can also kill neighboring tumor cells via the bystander effect.

BAT1308 is a recombinant fully human IgG4 anti-PD-1 monoclonal antibody produced in CHO cells by recombinant DNA technology and purified from clarified culture supernatant.

By binding PD-1 with high affinity and specificity, it blocks the PD-1/PD-L1/PD-L2 pathway to reverse immune suppression, activate T-cell function, enhance tumor immune surveillance and killing, and induce anti-tumor immunity.



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Study Design

Phase Ib Dose escalation study in participants with advanced solid tumors

KEY ELIGIBILITY:

- **Advanced solid tumors refractory to standard therapy (mainly ovarian, endometrial cancer patients)**

Study endpoints:

- Primary: ORy35 Ints:9(:R(l)-364(nly)2acco)]3(arydJETgo)4()4(8)11( )oraRETYydpYRy35sati

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Demographic and Clinical Characteristics

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All participants had received prior platinum-based chemotherapy, and 53.7% (29/54) had been treated with prior immunotherapy.

Of these, 36 participants were assigned to the 76 mg/m² group and 18 participants to the 84 mg/m² group.

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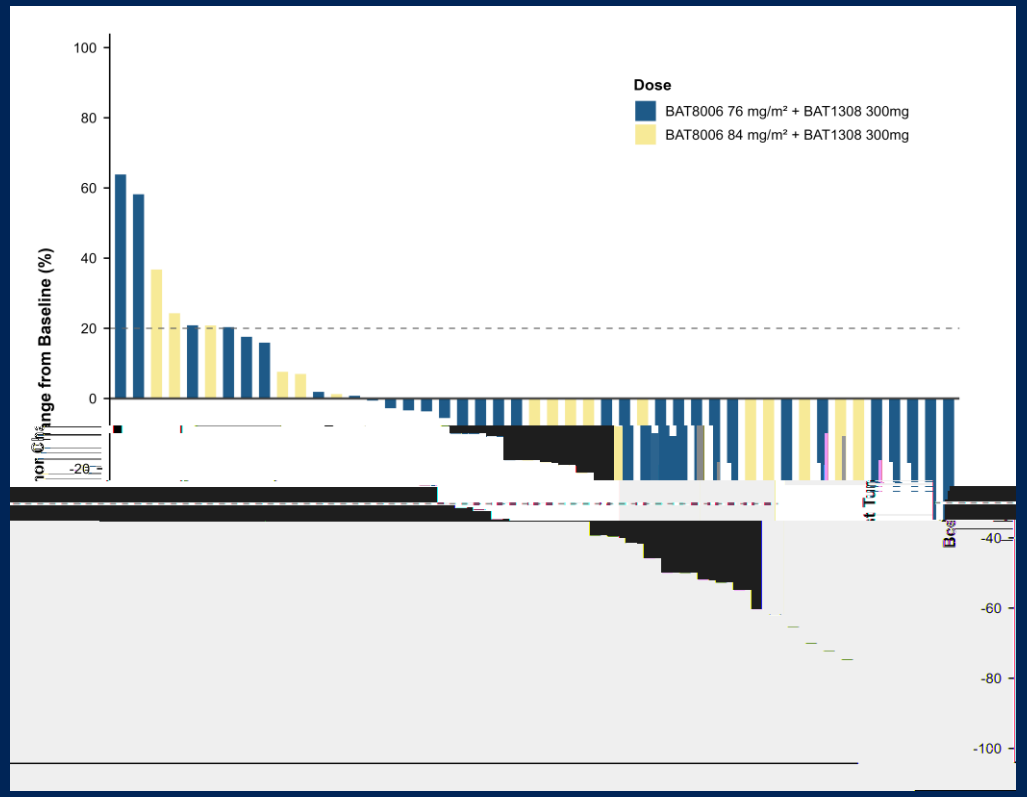
Efficacy Outcomes in EC Participants

As of April 20, 2026, a total of 30 participants in the 76 mg/m² group and 17 participants in the 84 mg/m² group were evaluable for efficacy per RECIST v1.1 criteria.

ORR Among EC-Evaluable Participants Across All Dose Cohorts

	76mg/m² (n=30)	84mg/m² (n=17)	Total (n=47)
CR, n (%)	0 (0%)	0 (0%)	0 (0%)
PR, n (%)	12 (40.0%)	6 (35.3%)	18 (38.3%)
SD, n (%)	12 (40.0%)	5 (29.4%)	17 (36.2%)
PD, n (%)	6 (20.0%)	6 (35.3%)	12 (25.5%)
ORR, n (%)	12 (40.0%)	6 (35.3%)	18 (38.3%)
DCR, n (%)	24 (80.0%)	11 (64.7%)	35 (74.5%)

Maximum Reduction of Target Lesions in EC Participants



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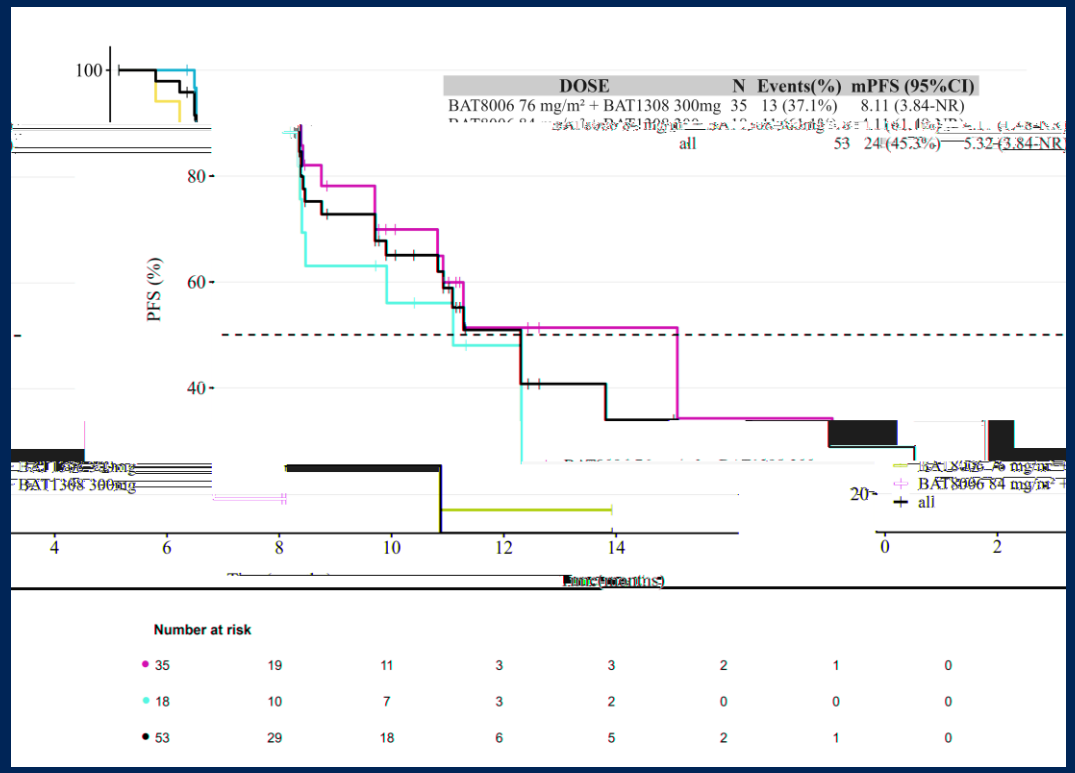
Efficacy Outcomes in EC Participants

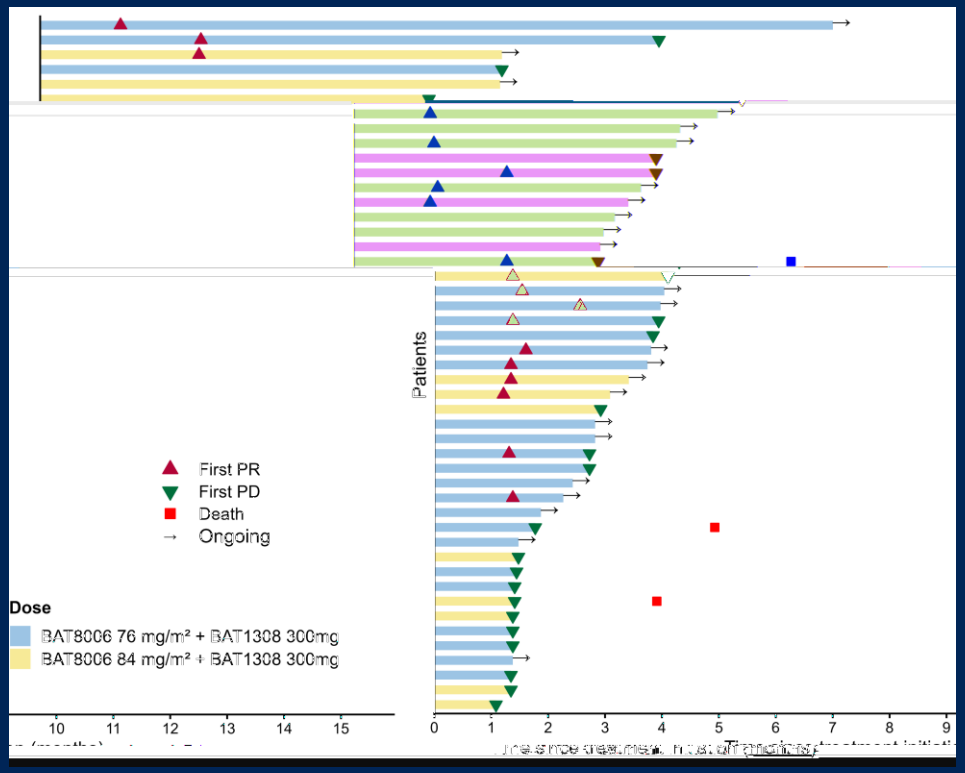
With a median follow-up of 3.81 months, the mPFS in 84 mg/m² group was 4.11 months (1.48 to NR), while the mPFS in 76 mg/m² group was 8.11 months (3.84 to NR).

Due to the short follow-up period to date, OS data have not matured.

K-M Curves of PFS in EC Participants



Swimmer Plot for Tumor Response Evaluation



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Overall Safety Results

As of April 20, 2026, 101 participants with advanced solid tumors have been enrolled in this study. Of these, 6 participants were enrolled in the 93 mg/m² dose group during the dose-escalation phase only, while 55 participants were enrolled in the 76 mg/m² dose group and 40 participants in the 84 mg/m² dose group.

In dose-escalation phase, no (0/6) DLT were observed at 76 mg/m² dose level. One (1/6) DLT were observed at 84 mg/m² dose level. Two (2/6) DLTs were observed at 93 mg/m² dose level.

The most common Grade 3 TEAEs were white blood cell count decreased, neutrophil count decreased, anaemia and platelet count decreased. These hematologic toxicities were clinically manageable and associated with favorable outcomes.

Safety Summary in Advanced Solid Tumor

	76 mg/m² (n=55)	84 mg/m² (n=40)
Any TEAEs	52 (94.5%)	40 (100%)
Grade 3 TEAEs	37 (67.3%)	32 (80.0%)
Grade 3 TRAEs	37 (67.3%)	31 (77.5%)
SAE	23 (41.8%)	21 (52.5%)
irAE	5 (9.1%)	6 (15%)
TEAEs leading to study drug dose reduction	10 (18.2%)	14 (35.0%)
TEAEs leading to study drug discontinuation	5 (9.1%)	4 (10.0%)
TRAEs leading to death	0	0

Most common Grade 3 TEAEs

PT Term	76 mg/m² (n=55)	84 mg/m2 (n=40)
Neutrophil count decreased	24 (43.6%)	28 (70.0%)
Anaemia	19 (34.6%)	16 (40.0%)
Platelet count decreased	18 (32.7%)	15 (37.5%)
White blood cell count decreased	17 (30.9%)	22 (55.0%)
Lymphocyte count decreased	9 (16.4%)	2 (5.0%)
Febrile neutropenia	2 (3.6%)	1 (2.5%)
Nausea	3 (5.5%)	0
Vomiting	2 (3.6%)	0
Asthenia	0	2 (5.0%)
Hyponatraemia	0	2 (5.0%)

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Conclusions

The safety profile of BAT8006 in combination with BAT1308 was generally tolerable, with no identified safety signals indicative of ILD or ocular toxicity. The main adverse events were hematologic toxicities, which were predictable and clinically manageable. The majority of gastrointestinal toxicities were Grade 1 or 2 in severity.

Preliminary efficacy data demonstrated promising antitumor activity of BAT8006 (' , expression status. This combination regimen may therefore benefit a broad patient population while achieving favorable efficacy.

BAT8006 dose level of 76 mg/m² exhibited a favorable benefit risk profile and is recommended as the RP3D for further development of this combination therapy.

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Acknowledgements

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