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Safety and Efficacy of BAT8006, a Folate Receptor α (FRα) Antibody Drug Conjugate, in Patients with Platinum-resistant Ovarian Cancer: Update on the Dose Optimization/Expansion Cohort of BAT-8006-001-CR Trial.

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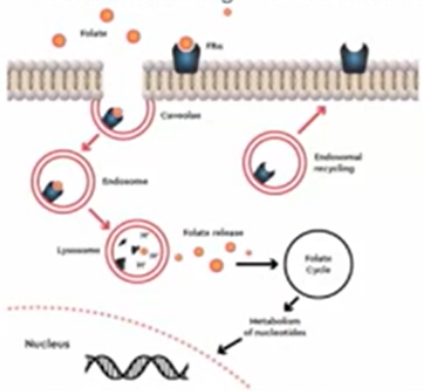
Background

▶ BAT8006 Design

BAT8006 was developed adopting a novel ADC platform technology with Exatecan as the payload tethered to a cleavable linker. The drug-to-antibody ratio (DAR) stands 7~8.

▶ Drug Target

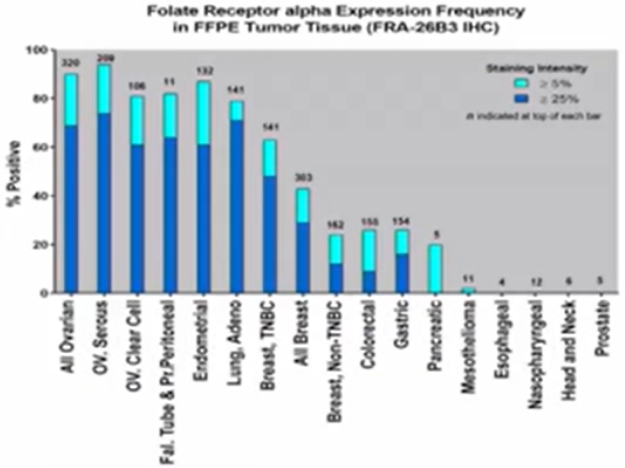
Folate receptor α (FRα) has a high affinity for reduced folates and folic acid and is responsible for the transport of folates for a number of reactions involving one-carbon transfer.



Birrer MJ,et al Oncologist(2019)
Sakai H,et al. Clin Transl Med (2021)

▶ Target Expression

FRα responsibled for the transport of folates for a number of reactions involving one-carbon transfer exhibits an increased expression on cell surfaces in multiple solid tumors, including ovarian, lung, breast and endometrial cancer, while demonstrating limited expression in normal tissue.



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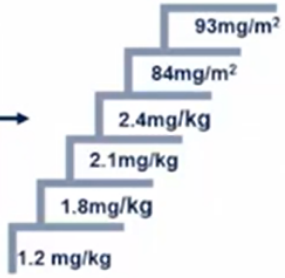
Study design

Part 1 Dose escalation study in subject with advanced solid tumors

KEY ELIGIBILITY CRITERIA:

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



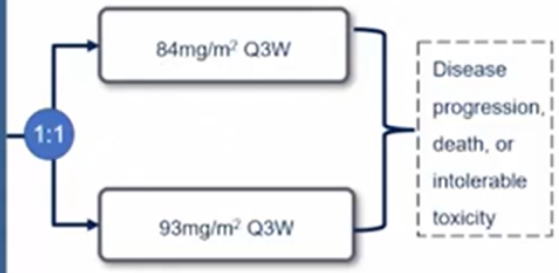
Study endpoints:

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

Part 2 Dose optimal/expansion study in subjects with Platinum-resistant Ovarian Cancer (PROC) cohort

KEY ELIGIBILITY CRITERIA:

- Platinum - resistant epithelial ovarian cancer, primary peritoneal cancer, and fallopian tube cancer with FRα PS 2+ ≥ 1%.
- With at least one measurable target lesion (according to RECIST v1.1).
- ECOG 0 to 1.



Study endpoints:

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

Based on E-R analysis, doses calculated using body surface area (BSA) exhibited a linear PK profile in terms of both efficacy response and safety profile. Two BSA-calculated doses were selected for the optimization study.

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Demographics and Antitumor Activity (PROC Cohort)

- A total of 82 patients with PROC, FRα expression ≥1%, and a history of 1 to 3 prior lines of therapy were randomized to the PROC cohort.
- Among them, 80.5% (66/82) subjects had previously received bevacizumab.
- With 38 and 31 subjects in the 84 mg/m² and 93 mg/m² groups were efficacy evaluable according to RECIST 1.1 criteria.

Baseline Characteristics of Subjects in PROC Cohort

	84mg/m² (n=43)	93mg/m² (n=39)
Age (Median, Min- Max)	55.0(41-74)	55.0(32-70)
ECOG 0/1	8/35	8/31
Priors Surgery (Yes/No)	42/1	38/1
Prior Radiotherapy (Yes/No)	2/41	3/36
Prior PARPi Therapy (Yes/No)	22/21	19/20
Prior Bevacizumab (Yes/No)	33/10	33/6
Prior Treatment Lines (Median, Min- Max)	2 (1-3)	2 (1-3)
Treatment Cycles (Median, Min-Max)	8 (2-20)	8 (1-20)
Treatment Ongoing (Yes/No)	9/34	10/29

The ORR in PROC Cohort

	84mg/m² (n=38)	93mg/m² (n=31)
ORR, n (%)	14* (36.8%)	13# (41.9%)
CR, n (%)	1 (2.6%)	1 (3.2%)
PR, n (%)	13 (34.2%)	12 (38.7%)
SD, n (%)	16 (42.1%)	14 (45.2%)
PD, n (%)	8 (21.1%)	4 (12.9%)
DCR, n (%)	30 (78.9%)	27 (87.1%)

* with 4 unconfirmed PR, # with 3 unconfirmed PR

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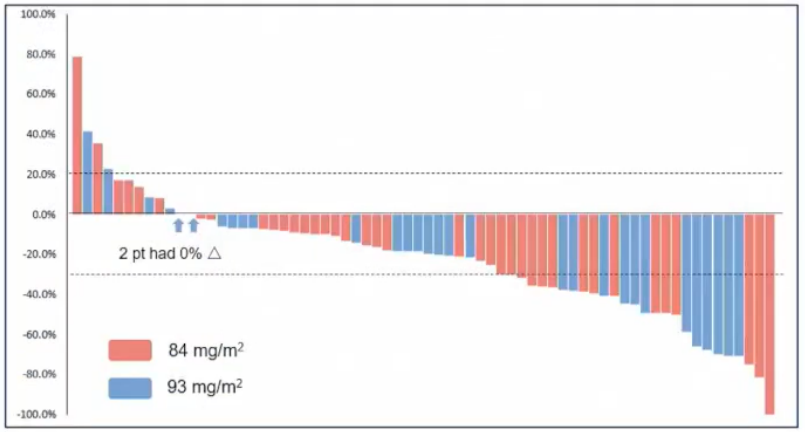
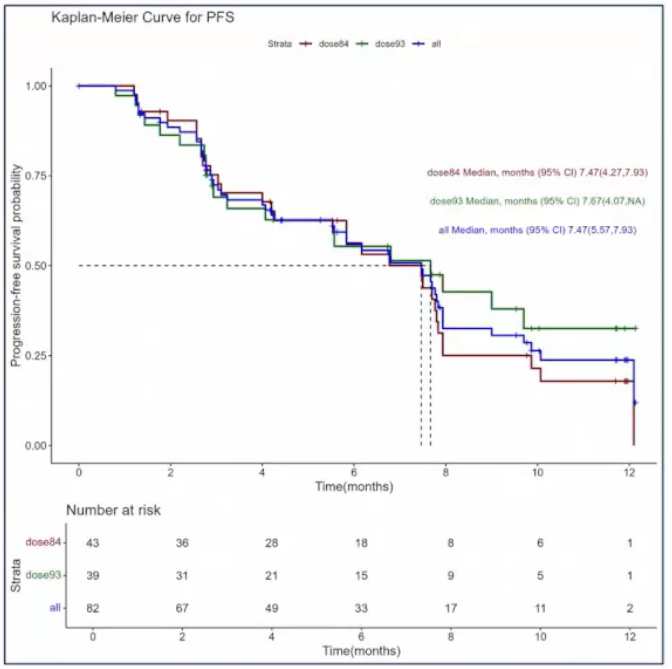
Efficacy in PROC Cohort

- With a median follow-up of 9.5 months, the mPFS in 84 mg/m² group was **7.47 months** (4.27 to 7.93), while the mPFS in 93 mg/m² group was **7.67 months** (4.07 to NA).
- The median OS have not been reached, with 6-month OS rates exceeding 75% for both groups.

Maximum Reduction of Target Lesions in PROC Cohort



K-M Curves of PFS in PROC Cohort



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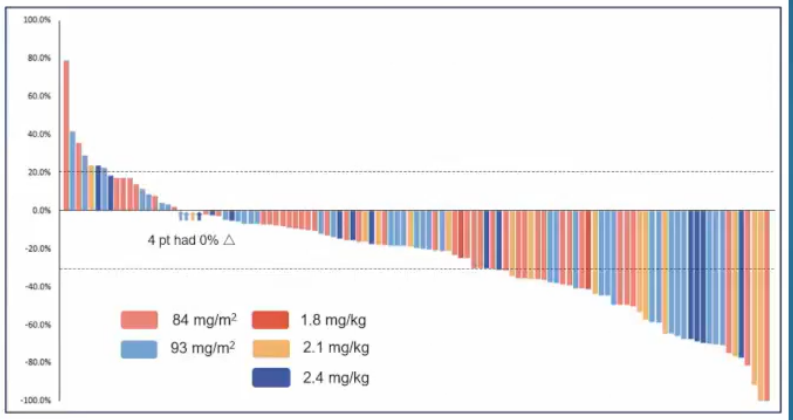
Efficacy in PRROC Subjects Across All Dose Cohorts

- 113 subjects with platinum-resistant/platinum-refractory ovarian cancer (PRROC) had undergone at least one tumor assessment after BAT8006 treatment, and were efficacy-evaluable according to RECIST V1.1 (including subjects from all dose cohorts, regardless of FRα expression levels).
- Among them, 31.9% (36/113) had previously received ≥ 3 lines of systemic anti-tumor therapy.

ORR in PRROC Subjects Across All Dose Cohorts

	All[1] (N=113)	FRα<50% (n=45)	FRα≥50% (n=68)	FRα ≥75% (n=31)
ORR, n (%)	46(40.7%)	17(37.8%)	29(42.6%)	15(48.4%)
CR, n (%)	2(1.8%)	0(0%)	2(2.9%)	2(6.5%)
PR, n (%)	44(38.9%)	17(37.8%)[2]	27(39.7%)[3]	13(41.9%)[4]
SD, n (%)	45(39.8%)	18(40%)	27(39.7%)	13(41.9%)
PD, n (%)	22(19.5%)	10(22.2%)	12(17.6%)	3(9.7%)
DCR, n (%)	91(80.5%)	35(77.8%)	56(82.4%)	28(90.3%)

Maximum Reduction of Target Lesions in PRROC Subjects Across All Dose Cohorts



1. Two subjects with unknown FRα expression levels were included in the FRα < 50% subgroup. 2. With 5 unconfirmed PR; 3. Wtih 6 unconfirmed PR; 4. With 2 unconfirmed PR.

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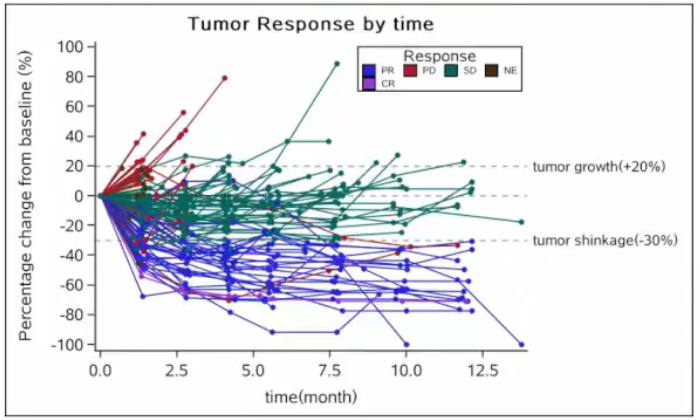
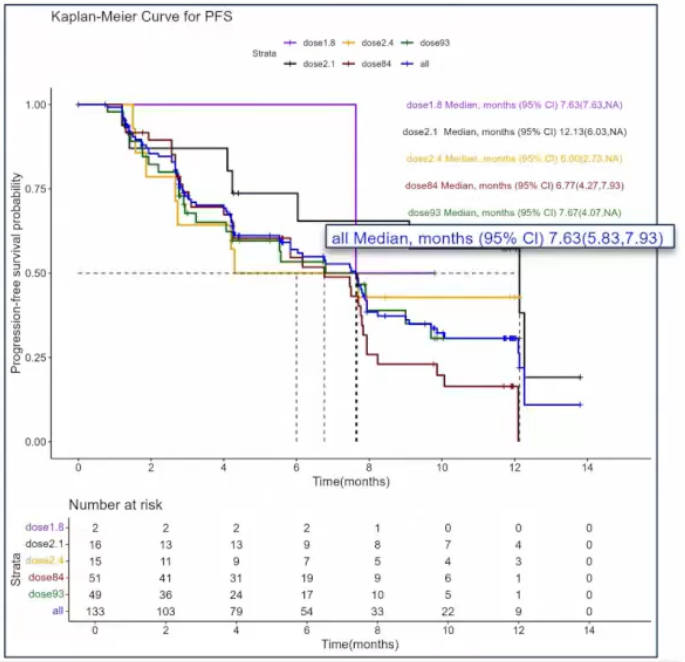
Efficacy in PRROC Subjects Across All Dose Cohorts

- With a median follow-up of 9.5 months, regardless of prior lines of treatment and FRα expression, the mPFS in 84 mg/m² dose level is **6.77 months** (4.27 to 7.93), in 93 mg/m² dose level is **7.67 months** (4.07 to NA).
- The mPFS among all PRROC patients is **7.63 months** (5.83 to 7.93), regardless the dose level.

Spider Plot of Percentage Change from Baseline in Target Lesion



K-M Curves of PFS in PRROC Subjects Across All Dose Cohorts



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Safety in Dose Optimization Study

- As of April 30, 2025, in the dose optimal/expansion study, 167 subjects with advanced solid tumors have been enrolled in 84 or 93 mg/m² cohort (80 subjects in each cohort were randomly assigned, additional 7 subjects in 84mg/m² were expanded). The median treatment cycles for these two cohorts were 6 (1~21) and 5 (1~22), respectively.

Safety Summary in Advanced Solid Tumor

	84mg/m² (n=87)	93mg/m² (n=80)
Any TEAE	85 (97.7)	80 (100)
Grade 3-4 TEAE	57 (65.5)	66 (82.5)
Related Grade 3-4 TEAE	55(63.2)	63 (78.8)
Serious TEAE	31 (35.6)	42 (52.5)
TEAE leading to study drug interruption	34 (39.1)	40 (50.0)
TEAE leading to study drug dose reduction	4 (4.6)	8 (10.0)
TEAE leading to study drug withdrawal	2 (2.3)	4 (5.0)
TRAE leading to death	0	0

Most common ≥Grade 3 TEAEs

SOC and PT	84mg/m² (n=87)	93mg/m² (n=80)
Anaemia	23(26.4)	44(55.0)
Febrile neutropenia	(0)	1(1.3)
Thrombocytopenia	18(20.7)	30(37.5)
Neutropenia	38(43.7)	44(55.0)
Leukopenia	23(26.4)	45(56.3)
Abdominal distension	(0)	2(2.5)
Intestinal obstruction	4(4.6)	4(5)
Vomiting	3(3.4)	3(3.8)
Asthenia	1(1.1)	2(2.5)
Herpes zoster	3(3.4)	(0)

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Conclusion

- The safety of BAT8006 was **tolerable** and **no ILD/ocular toxicity was reported**.
- The major adverse events were hematological toxicities and were predictable and manageable. Most of the gastrointestinal toxicities were Grade 1 or 2.
- The preliminary efficacy of BAT8006 was promising in patients with PRROC **regardless of the FRα expression levels**. BAT8006 **may benefit a broad patient population** while providing a superior efficacy.
- The dose optimal study in different doses supports the **determination of RP3D**.

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Ongoing Study of BAT8006

Study No.	Study Name
BAT-8006-003-CR (Phase 3)	A Randomized, Multicenter, Open-label Phase III Clinical Study Evaluating BAT8006 in Patients with Platinum-resistant Ovarian Cancer.
BAT8006+BAT1706-001-CR (Phase 2/3)	A Phase 2/3, Randomized, Open-label, Multicenter Study to Evaluate the Efficacy and Safety of BAT8006 as Maintenance Treatment in Patients with Platinum-sensitive Recurrent Ovarian Cancer
BAT8006+BAT1308-001-CR (Phase 1b/2)	A Multicenter, Open-label Phase 1b/2 Clinical Study Evaluating the Safety, Tolerability, Pharmacokinetic Characteristics, and Preliminary Efficacy of BAT8006 in Combination with BAT1308 in Patients with Advanced Solid Tumors.

Acknowledgements

- We extend our deepest gratitude to all the patients who participated in this study and their families for their invaluable contribution and unwavering support.
- Our sincere thanks also go to the investigators and staff at the participating study sites for their dedication and hard-work in the successful execution of this trial.
- This study was made possible by the support of Bio - thera Solution Co., Ltd.