Abstract 1046: A Phase Ib/IIa Study of BAT8010+BAT1006, an Anti-HER2 Monoclonal Antibody-Exatecan Conjugate Combined with an ADCC-Enhanced HER2 mAb in Patients with Advanced Solid Tumors : Results from the 1L HER2-Positive Breast Cancer Cohort

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BACKGROUND

- BAT8010 is a HER2 - targeted antibody - drug conjugate (ADC), 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.
- BAT1006 is a humanized monoclonal antibody. Unlike BAT8010, it targets a non-overlapping HER2 epitope. Its fucose - free nature enhances ADCC. Binding to HER2's extracellular domain II, it blocks HER2 heterodimerization with EGFR/HER3/HER4, inhibiting tumor cell growth and survival.
- This compares data of BAT1006 (n = 31) and Perjeta (n = 29, BO17929 study) in Her2+ breast cancer patients. BAT1006 patients had 1-6 prior treatment lines (87.5% ≥ 3L), versus Perjeta patients with only 1 prior line. BAT1006's ORR was 12.9%, DCR 64.5%, mPFS 4.1m; Perjeta's were 3.4%, 10.3%, 1.7m respectively. It is not a head - to - head study.

OBJECTIVE

Primary Objective

- To assess the safety and tolerability of BAT8010+BAT1006 in patients with advanced solid tumors, explore the maximum tolerated dose (MTD) and provide the recommended dose for subsequent studies.

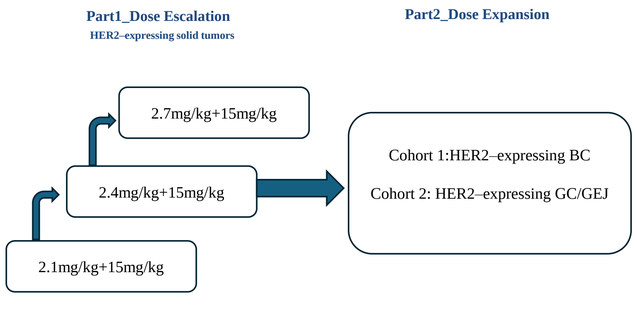
Secondary Objectives

- To evaluate the pharmacokinetic (PK) profiles and immunogenicity;
- To evaluate the preliminary anti-tumor efficacy;
- To explore the relationship between efficacy of BAT8010+BAT1006 and the expression of HER2 in tumor tissues and serum.

METHODS

Study design

•This is a multicenter, open-label Phase Ib/IIa dose escalation and dose expansion study with an accelerated titration and "3 + 3" dose escalation design. BAT8010 (2.4 mg/kg) + BAT1006 (15 mg/kg) dose was selected in the dose expansion study and patients are recruiting.



KEY INCLUSION & EXCLUSION CRITERIA

Inclusion:

- Histologically or cytologically confirmed advanced or metastatic solid tumors, unresponsive to standard treatments, intolerant to or declining standard therapies;
- At least one measurable target lesion according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1);
- Histologically or cytologically confirmed HER2-positive (IHC 3+ or FISH-positive) recurrent or metastatic breast cancer;
- No prior systemic anti-tumor therapy in the recurrent/metastatic setting, and a maximum of 1 line of endocrine therapy is permitted;
- In the (neo)adjuvant treatment setting, the interval from completion of systemic therapy (excluding endocrine therapy) to the onset of recurrence or metastasis is more than 12 months.

SAFETY & TOLERABILITY

- As of May 1st, 2026, total number of breast cancer subjects in the dose escalation and expansion phases combined (without distinguishing between phases or dose groups) is 87, of which 58 are in the 2.4mg/kg dose group.
- Most TEAEs were Grade 1/2; Grade 3 or higher AEs were mainly on hematologic toxicity,including neutropenia(55.2%), leukopenia (36.8%), thrombocytopenia (20.7%)and anemia (14.9%).
- No cases of interstitial lung disease (ILD)/pneumonitis were reported.
- The most common treatment-related adverse events (TRAEs) were included in **Table 1.**

Table 1: Treatment-Related Adverse Events in Breast Cancer Patients (≥20% overall incidence)

	Overall (N= 87)		2.4 mg/kg (N= 58)	
Preferred Term	All Grade n (%)	≥Grade 3 n (%)	All Grade n (%)	≥Grade 3 n (%)
Anaemia	62 (71.3%)	13 (14.9%)	46 (79.3%)	9 (15.5%)
Leukopenia	60 (69.0%)	32 (36.8%)	45 (77.6%)	23 (39.7%)
Neutropenia	59 (67.8%)	48 (55.2%)	45 (77.6%)	36 (62.1%)
Thrombocytopenia	38 (43.7%)	18 (20.7%)	29 (50.0%)	13 (22.4%)
Infusion related reaction	35 (40.2%)	2(2.3%)	25 (43.1%)	2(3.4%)
Alanine aminotransferase increased	34 (39.1%)	2(2.3%)	24 (41.4%)	2(3.4%)
Diarrhoea	32 (36.8%)	0(0.0%)	28 (48.3%)	0(0.0%)
Nausea	26 (29.9%)	0(0.0%)	23 (39.7%)	0(0.0%)
Aspartate aminotransferase increased	23 (26.4%)	1(1.1%)	18 (31.0%)	1(1.7%)
Asthenia	21 (24.1%)	1(1.1%)	19 (32.8%)	1(1.7%)
Vomiting	18 (20.7%)	0(0.0%)	16 (27.6%)	0(0.0%)

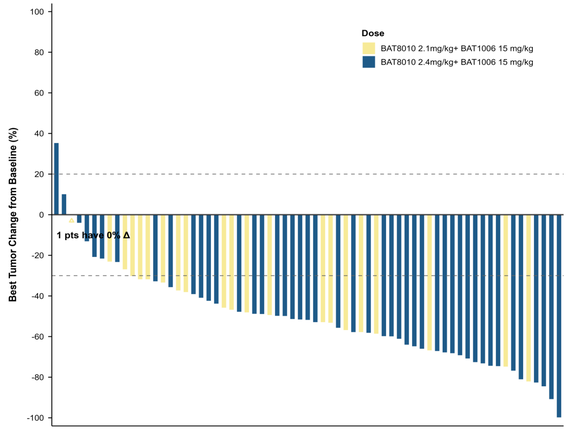
EFFICACY

- To the date of data cut-off May 1st 2026, 48 subjects with breast cancer were treated with BAT8010+BAT1006 dose of 2.4mg/kg + 15mg/kg and 21 subjects with 2.1mg/kg + 15mg/kg have received at least one tumor assessment;all patients were HER2+ first-line BC patients;
- 1 patient achieved CR, 42 PR, and 5 SD, yielding an ORR of 89.6% (42/48) ,cORR of 81.25% and a DCR of 100% (48/48);
- mPFS: not yet mature.

Table 2 The ORR in First-line BC Patients (N=69)

	First-line breast cancer 2.4mg/kg+15mg/kg	First-line breast cancer 2.1mg/kg+15mg/kg
N	48	21
PR	42	18
CR	1	0
SD	5	4
PD	0	0
ORR	89.6%	85.7%
DCR	100%	100%

Best Tumor Change from Baseline in First-line BC Patients



CONCLUSION

- **Safety aspect**: The combination of BAT8010 and BAT1006 has favorable safety. The main adverse events are hematological toxicities, which can be predicted and managed, and there is no reported interstitial lung disease (ILD).
- **Efficacy aspect**:BAT8010 in combination with BAT1006 is well-tolerated with manageable toxicity, and demonstrates promising preliminary antitumor activity in HER2-positive BC.
- **Ongoing research**: Dose expansion studies in this patient population are ongoing, and further confirmatory clinical trials are planned to initiate for the additional validation of its safety and efficacy.

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