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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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 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.

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.

Inclusion:

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.