TPS2694 **Poster Session**

An open-label, non-randomized, multi-center phase I study evaluating the safety, tolerability, pharmacokinetics and preliminary efficacy of bi-ligand-drug conjugate CBP-1018 in patients with advanced solid tumors.

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Background: Folate-receptor 1 (FOLR1) and prostate specific membrane antigen (PSMA) are overexpressed on tumor and angiogenic endothelial cells in solid tumors, including prostate cancer, renal cell cancer and lung cancer. CBP-1018 is a first-in-class bi-ligand drug conjugate targeting to both FOLR1 and PSMA, with a tubulin inhibitor payload, monomethyl auristatin E (MMAE). We herein introduce its first-in-human study which is designed based on the significant anti-tumor potency and acceptable safety profile in nonclinical studies. **Methods:** This study is a phase Ia/Ib, multicenter, open-label study enrolling patients with advanced solid tumor relapsed after previous standard therapies. The primary objective is to assess CBP-1018 safety, tolerability, dose limiting toxicity and maximum tolerated dose. Preliminary efficacy including objective response rate, duration of response and progression-free survival will be observed. Pharmacokinetics, immunogenicity and biomarkers will be also evaluated. This study includes 2 parts: Ia (Dose Escalation) and Ib (Dose Expansion). CBP-1018 is administrated iv Q2W (4 weeks/cycle) in Ia, with accelerated titration at lower doses (0.03 mg/kg and 0.06 mg/kg) and an i3+3 design at following doses (0.08 mg/kg, 0.10 mg/kg, 0.12 mg/kg and 0.14mg/kg, etc.). Subjects will be enrolled in 4 cohorts in Ib: metastatic castration resistant prostate cancer, advanced renal cell cancer, advanced lung squamous cell cancer, and other advanced solid tumors. Efficacy will be assessed every 8 weeks (±7days) according to RECIST 1.1, PCWG3 and PSA assessment (only for prostate cancer). Treatment will be continued untill disease progression or intolerable toxicity. Enrollment has been started in Nov. 2021 and is ongoing. Clinical trial information: NCT04928612. Research Sponsor: Coherent Biopharma (Suzhou) Co., Ltd.