TPS3187 **Poster Session**

Beamion PANTUMOR-1: A phase II, multicenter, multicohort, open-label trial to evaluate the efficacy and safety of the oral HER2-selective tyrosine kinase inhibitor zongertinib for the treatment of *HER2*-mutated or overexpressed/amplified solid tumors.

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Background: While it is well known that HER2 overexpression, amplification, and mutation drives various tumors, there remains an unmet need for effective, oral, HER2-targeted therapies. Zongertinib is an irreversible tyrosine kinase inhibitor (TKI) that selectively inhibits HER2 while sparing EGFR, thereby limiting associated toxicities. In the ongoing Phase Ia/Ib trial (NCT04886804), zongertinib showed manageable safety and confirmed responses in patients (pts) with HER2-overexpressed/amplified and *HER2*-mutant tumors (Wilding et al, *Cancer Discov.* 2024). Based on these encouraging data, the Beamion PANTUMOR-1 basket trial (NCT06581432) is evaluating the efficacy and safety of zongertinib monotherapy in pts with *HER2*-mutant or HER2-overexpressed/amplified solid tumors. **Methods:** In this global Phase II basket trial, ~200 pts with HER2-driven (*HER2*-mutant or HER2-overexpressed/amplified) tumors will be enrolled at ~60 sites in 13 countries. Pts will be enrolled to 10 cohorts: 8 cohorts of specific tumor types and 2 tumor-agnostic cohorts (see Table). The specific tumor type cohorts will initially recruit 10 pts, with potential for expansion to up to 20 pts after an interim analysis. In the tumor-agnostic cohorts, 20 pts will be recruited directly without an interim analysis. Pts will receive 120 mg zongertinib until disease progression, unacceptable toxicity, or withdrawal. Patients must be ≥18 years old, have documented HER2-positive (HER2-overexpressed/amplified) status or a *HER2* mutation (established by local testing), ≥1 measurable lesion outside the central nervous system, an ECOG performance score of 0 or 1, and have progressed following prior treatment or have no alternative treatment options. Exclusion criteria include *HER2*-mutant non-small cell lung cancer (NSCLC) and previous/concomitant malignancies. Primary endpoint is objective response, as assessed by central independent review according to RECIST v1.1. Secondary endpoints include duration of response, progression-free survival, disease control, occurrence of treatment-emergent adverse events, and health-related quality of life. Enrollment is ongoing. Clinical trial information: NCT06581432. Research Sponsor: Boehringer Ingelheim.

HER2 overexpression/ amplification cohorts	Tumor type	*HER2* mutation cohorts	Tumor type
Cohort 1	Urothelial cancer	Cohort 7	Urothelial cancer
Cohort 2	Biliary tract cancer	Cohort 8	Breast cancer
Cohort 3	Uterine cancer	Cohort 9	Gastroesophageal cancer
Cohort 4	Cervical cancer	Cohort 10	Other *HER2*-mutant solid tumors†
Cohort 5	Non-squamous NSCLC		
Cohort 6	Other *HER2* overexpressed/ amplified solid tumors*		

*Except breast cancer, gastric, gastroesophageal junction, or esophageal adenocarcinoma.
†Except NSCLC.