TPS3185 **Poster Session**

panSOHO: Phase II trial of BAY 2927088 in patients with unresectable or metastatic solid tumors other than NSCLC with *HER2*-activating mutations.

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Background: Human epidermal growth factor receptor 2 (*HER2*) gene mutations occur in approximately 3.5% of solid tumors, with a frequency varying from less than 1% to 9%, depending on the tumor type. BAY 2927088 is an oral, reversible tyrosine kinase inhibitor that potently inhibits HER2 and mutant epidermal growth factor receptor and has shown clinical benefit based on preliminary evidence from the Phase I/II SOHO-01 trial in patients with *HER2*-mutant non-small cell lung cancer (NSCLC; PL04.03 presented at IASLC 2024 World Conference on Lung Cancer), an indication for which the FDA has granted Breakthrough Designation. Here we introduce the panSOHO trial evaluating the efficacy and safety of BAY 2927088 in patients with unresectable, locally advanced or metastatic solid tumors with *HER2*-activating mutations. **Methods:** panSOHO is a Phase II, open-label, multicenter, multinational, single-arm basket trial of BAY 2927088 in patients with unresectable or metastatic solid tumors with *HER2*-activating mutations (NCT06760819), and will be conducted in the USA, Europe, and the Asia-Pacific region. Eligibility criteria include patients aged ≥18 years with: documented histologically or cytologically confirmed, locally advanced or metastatic solid tumor cancer (colorectal, biliary tract, bladder and urothelial tract, cervical, endometrial, or other solid tumor); documented activating HER2 mutation; ≥1 measurable lesion per RECIST v1.1; and previous standard therapy or no satisfactory alternative treatment options. Key exclusion criteria include primary diagnosis of NSCLC, treatment with a HER2 tyrosine kinase inhibitor, untreated active brain metastases, and leptomeningeal disease. Overall, 111 eligible patients will receive BAY 2927088 p.o. 20 mg twice daily in 3-week cycles until disease progression, unacceptable toxicity, or study withdrawal. The primary outcome is BAY 2927088 efficacy on objective response rate per RECIST v1.1 as assessed by blinded independent central review (BICR). Secondary outcomes include BAY 2927088 efficacy on time to response, duration of response, disease control rate, and progression-free survival per RECIST v1.1 by BICR, and overall survival, and BAY 2927088 safety and tolerability. Impact of BAY 2927088 on patient quality of life will be evaluated by EORTC QLQ-C30. Enrollment is open. Clinical trial information: NCT06760819. Research Sponsor: Bayer AG.