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Interim analysis results of surufatinib in US patients with neuroendocrine tumors (NETs)

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BACKGROUND: Surufatinib is a targeted inhibitor of tyrosine kinases VEGFR1, 2, & 3, FGFR1, and CSF-1R. A manageable safety profile, and statistically significant efficacy have previously been demonstrated in patients with advanced NETs of extrapancreatic (epNET) and pancreatic (pNET) origin in 2 phase 3 randomized trials conducted in China (SANET-ep & SANET-p [Xu, 2020]).

METHODS: This Phase 1b, dose escalation/expansion study was conducted to evaluate and confirm the efficacy and safety of surufatinib in US patients. The recommended phase 2 dose determined and used for dose expansion was 300mg QD. The primary endpoint of dose escalation was investigator-assessed PFS rate at 11 mo.

RESULTS: 32 patients with heavily pre-treated progressive NETs (16 epNET and pNET, respectively) were enrolled. 65.6% of patients had received ≥ 3 prior lines of treatment; all patients previously received everolimus and/or sunitinib. PFS rate at 11 mo was 51.1% (95% CI: 12.8, 80.3) for patients with epNETs; and 57.4% (95% CI: 28.7, 78.2) for patients with pNETs. mPFS was 11.50 mo (95% CI: 6.47, 11.50), and 15.18 mo, (95% CI: 5.19, NR), for patients with epNETs and pNETs, respectively. An ORR of 6.3% was observed for epNET patients, and 18.8% for pNET patients. A disease control rate of 90.6% (95% CI: 75.0, 98.0) was observed for all NET patients. All patients reported at least one adverse event, and 24 patients (75%) reported AEs $\geq$ grade 3. The most common AEs of any grade reported were: fatigue (46.9%), hypertension (43.8%), proteinuria (37.5%), diarrhea (34.4%), vomiting (28.1%), and nausea (25.0%). The most commonly

reported AEs $\geq$ grade 3 ($>5\%$) were hypertension (37.5%), diarrhea (9.4%), proteinuria, dysphagia, and anemia (6.3%).

CONCLUSION: Surufatinib has demonstrated antitumor activity in heavily pretreated US patients with progressive NETs with a manageable safety profile that is consistent with 2 completed phase 3 studies.

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