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Subgroup Analysis by Ki-67 and Primary Tumor Origins of the Randomized, Placebo-controlled Phase 3 Study of Surufatinib in Advanced Well-differentiated Extrapancreatic Neuroendocrine Tumors (SANET-ep)

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BACKGROUND: Surufatinib showed significant prolonged progression-

free survival (PFS) benefit with a tolerable safety profile in patients with extrapancreatic neuroendocrine tumors (NETs) in a phase 3 study (SANET-ep). Here we present the post-hoc subgroup efficacy analysis according to Ki-67 and primary tumor origins from SANET-ep study.

METHODS: Totally, 198 patients were randomized (2:1) to surufatinib or placebo. The post-hoc subgroup analyses were performed based on Ki-67 subcategories: < 3% (n = 21 vs 11), 3-10% (n = 78 vs 44), > 10% (n = 30 vs 14); and primary tumor origin subcategories: foregut (n = 49 vs 29), midgut (n = 12 vs 6), hindgut (n = 40 vs 17), others (n = 8 vs 5) and unknown (n = 20 vs 12). The primary endpoint was investigator-assessed PFS, and the secondary endpoints mainly included objective response rate (ORR) per RECIST 1.1.

RESULTS: Median PFS was significantly prolonged in subgroups of Ki-67 3_10% (HR 0.47, 95% CI 0.29-0.74) and Ki-67 >10% (HR 0.14, 95% CI 0.05-0.40) with surufatinib versus placebo. ORR in the subgroups of Ki-67 <3%, 3-10%, >10% were 4.8% (95% CI 0.1-23.8), 7.7% (95% CI 2.9-16.0) and 20.0% (95% CI 7.7-38.6) respectively with surufatinib, versus none with placebo. Median PFS was significantly longer in the subgroups of foregut (HR 0.29, 95% CI 0.15-0.54) and hindgut (HR 0.35, 95% CI 0.18-0.67) with surufatinib versus placebo. ORR in the subgroups of foregut, midgut and unknown origin were 18.4% (95% CI 8.8-32.0), 16.7% (95% CI 2.1-48.4) and 10.0% (95% CI 1.2-31.7) respectively with surufatinib, versus none with placebo.

CONCLUSION: Results of this post-hoc analysis were consistent with the primary reports on surufatinib in the SANET-ep primary analysis, and improved outcomes were observed across major subgroups in patients with advanced well-differentiated extrapancreatic NETs.

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