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Health-related Quality-of-life Analysis of Surufatinib Versus Placebo for Advanced Neuroendocrine Tumors: Pooled Results From Two Phase 3 Studies (SANET-p and SANET-ep)

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BACKGROUND: Two previous phase 3 studies (NCT02589821, NCT02588170)

have demonstrated surufatinib significantly improved progression-free survival compared with placebo in patients with advanced pancreatic neuroendocrine tumors (NETs) and extrapancreatic NETs. We performed a pooled analysis of the two studies to assess the overall health-related quality of life (HRQoL) among these patients.

METHODS: Patient-reported HRQoL was measured at baseline, Day 15 of cycle 1, Day 1 of each subsequent cycle and at the time of discontinuation using EORTC QLQ-C30 and QLQ-G.I.NET-21. Time until definitive deterioration (TuDD) was defined as the time from randomization to deterioration of 10 points in domain score compared with baseline score (without subsequent observations of deterioration of <10 point or any improvement compared to baseline score), or death due to any cause. Change of scores from baseline were evaluated using longitudinal method. TuDD was assessed with Kaplan-Meier estimators and unstratified Cox models. P-values were derived from unstratified log rank test.

RESULTS: Patients were randomized (2:1) to surufatinib (N=242) and placebo (N=128). The compliance rate of EORTC QLQ-C30/GI.NET21 was >99% in both groups at baseline. For TuDD, surufatinib significantly decreased risk of deterioration in dyspnea (HR 0.58, $p=0.0058$), but significantly increased risk of deterioration in diarrhea (HR 2.91, $p=0.0001$), compared to placebo using QLQ-C30 Scales. No significant difference was observed in TuDD between two treatment groups in the remaining QLQ-C30 and QLQ-G.I.NET-21 scales. Least-squares mean differences from baseline to week 40 showed a favored trend of surufatinib at most visits for most QLQ-C30 and QLQ-G.I.NET-21 scales, except diarrhea QLQ-C30 scale (increase of 14.9 points vs 1.1 points, $p<0.0001$) and muscle/bone pain symptoms QLQ-GI.NET21 scale (increase of 9.3 vs 3.9, $p=0.0303$).

CONCLUSION: Surufatinib showed a comparable effect on HRQoL to placebo for patients with advanced NETs.

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