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Preliminary clinical activity of surufatinib combined with octreotide LAR in patients with G1/2 gastroenteropancreatic neuroendocrine tumor (GEP-NET)

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BACKGROUND

Surufatinib targets VEGFR1-3, FGFR1 and CSF1R, is a novel oral tyrosine kinase inhibitor (TKI) with dual antiangiogenic and immunomodulatory activities. It has been approved for the treatment of well-differentiated neuroendocrine tumors. Octreotide LAR, a somatostatin analogue, has been approved for the treatment of G1/G2 GEP-NET. This study aims is to investigate the efficacy and safety of surufatinib combined with octreotide LAR in the treatment of G1/G2 GEP-NET.

METHODS

This single-arm, prospective, open-label phase II clinical study included patients aged 18-75 years with unresectable locally advanced or distant metastasis G1/G2 GEP-NET, ECOG PS 0-1, and adequate organ and bone marrow function. Patients received surufatinib (300 mg, po, qd) and octreotide LAR (30mg, sc, q4w) until disease progression or unacceptable toxicity. The primary endpoint was 6-month progression-free survival (PFS) rate. The secondary endpoints were PFS, overall survival (OS), objective response rate (ORR), disease control rate (DCR) and safety.

RESULTS

As of August 5, 2024, 8 patients were enrolled, and 7 were assessable, with a median age of 59 years (range 40-66), and 57.1% females. Most were G2 (71.4%) with a median Ki-67 index of 5% (range: 2-10%). The primary sites included rectum (42.9%), pancreas (28.6%), gastric (14.3) and small intestine (14.3%). All of them had liver metastases. 28.6% had prior anti-tumor therapy. With 15.7 months median follow-up, the 6-month and 12-month PFS rates were 100.0% and 66.7% (95%CI 37.9-100.0%). 2 patients progressed, 5 remain on treatment, 4 beyond 14 months (24.6, 20.1, 14.9, 14.2 months). The ORR and DCR were 28.6% and 100.0%, respectively. The most common treatment-related adverse events (TRAEs) were proteinuria (62.5%), lactate dehydrogenase increased (37.5%) and thyroid stimulating hormone increased (37.5%). Grade 3 TRAEs were proteinuria (12.5%) and hypertension (12.5%). No grade 4 TRAEs or deaths were reported.

CONCLUSIONS

This first study demonstrates promising antitumor activity and manageable safety of surufatinib plus octreotide LAR in G1/2 GEP-NET patients. The results support further evaluation of the therapy in a larger population. This trial is ongoing and updated data will be presented in the future.

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