C-33

QOL Improvements in NETTER-1 Phase III Trial in Patients with Progressive Midgut Neuroendocrine Tumors

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BACKGROUND: Aims: Neuroendocrine tumor progression is associated with deterioration in quality of life, both due to tumor and hormone-related symptoms. We aim to determine the impact of treatment on time to clinically relevant change (deterioration) in health-related quality of life (HRQoL).

MATERIALS: The NETTER-1 trial is an international phase III study which enrolled patients with progressive, somatostatin receptor positive midgut neuroendocrine tumors. Patients were randomized to receive treatment with 177Lu-DOTATATE (177Lu; Lutathera) versus high-dose (60 mg) Octreotide LAR (Oct). EORTC questionnaires QLQC-30 and G.I.NET-21 were assessed during the trial to determine the impact of treatment on HRQoL.

METHODS: Patients completed EORTC QLQC-30 G.I.SNET-21 questionnaires at baseline and every 12 weeks thereafter until progression was centrally confirmed. QoL scores were converted to a 100-point scale according EORTC instructions and individual changes from baseline scores were assessed. The time to deterioration was defined as the time (in months) between randomization and the first QoL deterioration ≥10 points for each patient in the corresponding domain scale. This magnitude of variation was considered clinically relevant.

RESULTS: Time to QoL deterioration was significantly longer in the 177Lu-DOTATATE arm vs the control arm for the following domains: global health status (hazard ratio (HR) 0.406; p=0.0006), physical functioning (HR 0.518; p=0.0147), role functioning (HR 0.580; p=0.0298), fatigue (HR 0.621; p=0.0297), pain (HR 0.566; p=0.0247), diarrhea (HR 0.473; p=0.0107), disease related worries (HR 0.572; p=0.0176) and body image (HR 0.425; p=0.0058). In the other domains time to deterioration did not reach statistical significance between the arms.

CONCLUSION: This analysis demonstrates that 177Lu-DOTATATE provides a significant quality of life benefit for patients with progressive midgut NETs compared to high-dose octreotide, in addition to the meaningful increase in progression-free survival already reported.