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# Lanreotide Autogel Significantly Improves Tumor Progression-Free Survival in Patients with Non-Functioning Gastroenteropancreatic Neuroendocrine Tumors: Results of the CLARINET Study

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**Background:** Somatostatin analogs (SSAs) provide good symptom control in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Clinical studies in mixed populations and limited numbers of patients with functioning or non-functioning NETs suggest that SSAs also stabilize tumor growth. The objective of CLARINET was to evaluate the antiproliferative effects of the SSA lanreotide Autogel (Depot in the US) in a large population of patients with non-functioning NET.

**Methods:** CLARINET was a 96-week, double-blind, placebo-controlled phase 3 trial of lanreotide Autogel in patients with well- or moderately-differentiated non-functioning GEP-NETs and a proliferation index (Ki67) of <10% (NCT00353496). A total of 204 patients stratified by prior tumor progression status and presence/absence of previous therapies were randomized to treatment with lanreotide Autogel 120 mg (n=101) or placebo (n=103). The primary endpoint was progression-free survival (PFS; using Response Evaluation Criteria In Solid Tumors). Two baseline computed tomography scans (≥12 weeks apart) were performed, followed by additional scans at regular intervals up to 96 weeks. Secondary endpoints included proportion of patients alive and without tumor progression at 48 and 96 weeks, time to progression, overall survival, quality of life, tumor biomarkers, pharmacokinetic parameters, and safety.

**Results:** Lanreotide Autogel 120 mg achieved a statistically significant improvement over placebo in PFS over 96 weeks: median PFS was not reached with lanreotide and was 18 months with placebo (hazard ratio 0.47 [95% CI 0.3-0.7], p=0.0002). The safety/tolerability observed in the study was consistent with the known safety profile of lanreotide Autogel. Further results will be presented at the time of the NANETS meeting.

**Conclusion:** CLARINET is the first large-scale, randomized, placebo-controlled study, inclusive of both gastrointestinal and pancreatic NETs, which provides clear evidence for the antiproliferative activity of an SSA. This should help to confirm the place of lanreotide Autogel in the treatment algorithm of patients with non-functioning GEP-NETs.