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Evaluation of the Efficacy and Safety of Lanreotide on Tumor Growth Stabilization in Patients with Progressive NETs Who Are Not Eligible for Treatment with Surgery or Chemotherapy

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Background: Somatostatin analogs (SSAs) are the treatments of choice for hormonal symptoms associated with NETs. Clinical studies have suggested stabilization of or, in rare cases, a partial response in the tumor mass. No data have been presented previously relating to the antitumoral activity of SSAs as sole treatment in documented progressive NETs. Thus, we undertook a phase II trial (NCT0032646) to evaluate the efficacy of lanreotide Autogel 120 mg on tumor growth stabilization in this patient population.

Methods: Thirty Caucasian patients from 17 Spanish hospitals with advanced and/or metastatic well-differentiated NETs that were progressive within the last 6 months were treated with lanreotide Autogel 120 mg every 28 days until progression. Exclusion criteria: SSA treatment during the previous 6 months; chemotherapy/interferon treatment during the previous 4 weeks. Radiologic evaluation was performed every three cycles. The primary endpoint was progression-free survival

(PFS) per central blind review (using RECIST criteria). Clinical baseline characteristics were: median (range) age, 63 (40-78) years; male/female, 50%/50%; median (range) time since diagnosis, 5.5 (0.2-22.2) years; ECOG 0/1/2, 63%/30%/ 7%; foregut/midgut/unknown, 47%/40%/ 13%; median (range) Ki index, 2.0 (0.0 - 20.0); functioning/non-functioning, 63%/37%; previous pharmacologic treatment naive/chemotherapy/ interferon/SSAs, 50%/33%/23%/20%.

Results: Median PFS (95% CI) was 12.9 (7.9-16.5) months both in intention-to-treat and per-protocol populations. Best tumor responses were: 4% partial response/89% stable disease/7% disease progression. Ki 67 index was the most likely prognostic factor for PFS (n=21; hazard ratio, 1.17; p=0.018). One patient discontinued treatment due to adverse events (AE). Only one severe treatment-related AE was detected (aerophagia). No impairment in EORTC QLQ-C30 for the whole group was detected during treatment.

Conclusions: In this study, sole treatment with lanreotide Autogel 120 mg in progressive NET patients provided a median PFS >12 months with very low toxicity. This apparent tumoral control effect should be confirmed in an ongoing phase III trial (CLARINET, NCT00842348).