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Somatuline® Autogel® 120 mg (lanreotide) Evaluation of Tumor Progression-Free Survival in Patients with Non-Functioning Entero-Pancreatic Endocrine Tumors: An Ongoing, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study (the CLARINET Study)

Joëlle Blumberg[1], Edda Gomez-Panzani[2], Séverine Latapie-Martinez[1]and Nilani Liyanage[1]

[1]Ipsen Pharma, Les Ulis Cedex, France 91940; [2]Ipsen, US, Brisbane, CA 94005

Background: Lanreotide (Somatuline® Autogel®) is a somatostatin analogue that is approved in >50 countries for the treatment of acromegaly and symptoms associated with carcinoid syndrome, but for now is approved in the US for the treatment of acromegaly only. Lanreotide has a prolonged-release formulation that is presented as a ready-to-use, pre-filled syringe administered via deep subcutaneous injection every four weeks. The anti-tumor activity of lanreotide and its effect on tumor progression has not been fully assessed; it has only been evaluated in uncontrolled studies in a limited number of patients. The current study evaluates the effect of lanreotide versus placebo on progression-free survival in patients with well or moderately differentiated non-functioning entero-pancreatic endocrine tumors.

Methods: This is an ongoing, 96-week, double-blind, randomized, stratified comparative, placebo-controlled, parallel-group, multicenter Phase 3 study. Randomization is stratified by the presence/absence of tumor progression and previous therapies to minimize the risk of an imbalance between the groups. Patients randomly receive either 120 mg lanreotide every four weeks or placebo. The key study inclusion criteria are: age ≥18 years; metastatic disease and/or locally advanced inoperable tumor; non-functioning entero-pancreatic tumor of unknown origin or with a known primary location in the pancreas, mid-gut or hindgut, or an adequately controlled gastrinoma; well or moderately differentiated tumor (Ki67 <10%); and a positive octreoscan with target lesions ≥grade 2 at screening or within 6 months prior to study entry. The primary endpoint is time to either disease progression (measured using the RECIST criteria) or death, occurring within 96 weeks after first treatment administration. The objective is to randomize

200 patients with 90% power to detect a difference of 0.20 in the expected rate of progression or death between the groups.