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The CLARINET Study – Assessing the Effect of Lanreotide Autogel on Tumor Progression-Free Survival in Patients with Non-Functioning Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

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Background: Somatostatin analogs (SSAs) provide good symptom control in NET patients. Clinical studies suggest SSAs also stabilize tumor growth. In a previous double-blind study (PROMID) in a mixed functioning and non-functioning gastroenteroNET population (n=85), octreotide LAR significantly increased time to tumor progression versus placebo. No similar well-controlled study has previously been conducted with lanreotide Autogel (lan-ATG). Thus, the CLARINET study, a double-blind, placebo-controlled trial, has been undertaken to assess the effect of lan-ATG 120 mg on progression-free survival in patients with non-functioning GEP-NETs.

Methods: CLARINET is a 96-week, multinational study being conducted in collaboration with UKI NETS and ENETS in 200 patients with well or moderately differentiated non-functioning GEP-NETs and Ki67 <10%. Patients are stratified by prior tumor progression status and presence/absence of previous therapies, and treated with lan-ATG 120 mg. The primary endpoint is time to either disease progression (using RECIST criteria) or death. Two baseline CT scans (≥12 weeks apart) are performed, followed by additional scans at intervals up to 96 weeks. Secondary endpoints include proportion of patients alive and without tumor progression at 48 and 96 weeks, time to progression, overall survival, safety, quality of life, plasma chromogranin A levels and pharmacokinetic parameters.

Results: By mid-June 2011, 203 patients were included. Preliminary baseline data for the first 186 patients (95 males; mean [SD] age, 62.5 [10.3] years) are available: tumors most commonly originated in the pancreas (n=81, 44%) or small intestine (n=62, 33%), with the location of the primary unknown in 22 patients; seven patients had progressive disease; and 28 had received previous therapy. Thus far, the drug safety monitoring committee has identified no safety concerns. Final results are expected in 2013.

Conclusion: CLARINET will provide important information on the anti-tumoral activity and safety of lan-ATG, specifically in a large cohort of patients with non-functioning GEP-NETs.