Change in Patient-Reported Symptom Control in Patients With Neuroendocrine Tumors Treated With Lanreotide Depot

Edward M. Wolin1; Susan Pitman Lowenthal2; George A. Fisher, Jr3; Nilani Liyanage4; Beloo Mirakhur2; Rodney F. Pommier5; Montaser Shaheen6; Aaron I. Vinik7

1Montefiore Einstein Center for Cancer Care; 2Ipsen Biopharmaceuticals; 3Stanford University; 4Ipsen, France; 5Oregon Health and Science University, Portland, OR; 6University of Arizona Cancer Center; 7Eastern Virginia Medical School

BACKGROUND: Lanreotide depot/Autogel significantly reduced short-acting octreotide use for carcinoid syndrome (CS) symptom control in neuroendocrine tumor (NET) patients vs placebo, in the 16-week double-blind (DB) phase of ELECT. To further characterize the impact of lanreotide on diarrhea and flushing symptoms, we present patient-reported data submitted daily via Interactive Voice (Web) Response Systems (IVRS).

METHODS: ELECT included 16-week DB and 32-week open-label phases, and a long-term open-label extension. The primary endpoint was mean percentage of days of short-acting octreotide use for symptom control in the DB phase. Adults with confirmed NET/NET of unknown location with liver metastases and history of CS were randomized to lanreotide 120 mg or placebo/4 weeks. All were able to use short-acting octreotide as needed. Patients recorded symptom frequency and severity daily using IVRS. Data were analyzed using analysis of covariance models with country, prior somatostatin analog status, and baseline symptoms as covariates. Average combined scores of daily frequency and...
severity of symptoms/patient/day were calculated by multiplying frequency (eg, 0=no symptoms) with respective severity scores (1=mild, 2=moderate, 3=severe/missing).

**RESULTS:** Of 115 patients, 59 were randomized to lanreotide and 56 to placebo. In the DB phase, ~70% of lanreotide-treated patients experienced decreased average combined scores of daily frequency and severity of diarrhea vs <55% of placebo-treated patients. There was a smaller difference when comparing flushing scores. For diarrhea and/or flushing, ~75% of lanreotide-treated patients experienced decreases vs <60% of placebo-treated patients. Median changes in scores for diarrhea and/or flushing were -1.46 and -0.57 for lanreotide and placebo, respectively.

**CONCLUSION:** Results of this analysis confirm the efficacy of lanreotide for symptom control in patients with NETs and CS. The cumulative distribution function of changes in average combined symptom scores further characterizes the effect of lanreotide on symptom control in this population.