C-28
Lanreotide for the Prolonged Control of Carcinoid Syndrome (CS) in Somatostatin Analog (SSA)-Naïve or -Experienced Patients

Edward Wolin1; George Fisher2; Susan Pitman Lowenthal3; Beloo Mirakhur3; Rodney Pommier4; Montaser Shaheen5; Aaron Vinik6

1Tisch Cancer Institute at Mount Sinai; 2Stanford University School of Medicine; 3Ipsen Biopharmaceuticals, Inc.; 4Oregon Health & Science University; 5University of New Mexico Comprehensive Cancer Center; 6Eastern Virginia Medical School

BACKGROUND: Mean percentage of usage days (MPUD) with rescue subcutaneous octreotide (sc-OCT) was significantly lower for lanreotide depot/autogel (LAN) 120 mg than placebo (PBO) during 16-week double-blind (DB) phase of the ELECT study. We examined prospective data on sc-OCT or other rescue medication use during DB and initial open-label (IOL) phase of ELECT to evaluate impact of LAN on prolonged relief of CS symptoms.

METHODS: Adults with neuroendocrine tumors (NETs) and CS history, with/without prior SSA use, were randomized to 16 weeks DB LAN 120mg/sc or PBO q4w, followed by a 32-week IOL LAN phase. Prospectively collected data on sc-OCT or other rescue medication use during screening, DB, and IOL were analyzed.

RESULTS: During DB phase, LAN was associated with less frequent rescue sc-OCT use (least squares MPUD) 33.7% LAN versus 48.5% PBO; P=0.02. Through the 32-week LAN IOL phase, sc-OCT use in the DB LAN group decreased to 27.1%. Following crossover from PBO to active treatment, sc-OCT use in the DB PBO group decreased from 48.5% to 20.9% during IOL period. Use of other rescue medications at baseline were: 12.9% LAN; 8.3% PBO; no significant decreases
were observed with LAN treatment during the DB phase (8.9% LAN vs 6.3% PBO). Use in the DB LAN group remained relatively unchanged through the IOL phase (8.9% LAN DB; 8.8% LAN IOL). Following crossover from PBO to treatment, PBO group exhibited a decrease in use of other rescue medications from 6.3% to 3.1% during IOL. Stratified by SSA therapy (naïve/prior SSA therapy), no differences were observed in sc-OCT or other rescue medication use between cohorts. Use of rescue medications in individual cohorts was similar to the overall group.

CONCLUSION: These results demonstrate LAN is effective for the prolonged control of CS symptoms in SSA-naïve or SSA-experienced (LAR or short-acting OCT) NET patients.