

# C10

## The Efficacy and Safety of Pasireotide (SOM230) in the Treatment of Patients with Metastatic Neuroendocrine Tumors (NET) Refractory or Resistant to Octreotide LAR

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**Background:** Pasireotide (SOM230) is a novel multi-receptor targeted somatostatin analogue with high binding affinity for sst<sub>1,2,3</sub> and sst<sub>5</sub>. Therefore, pasireotide may offer improved efficacy compared with other somatostatin analogues in patients with NET unresponsive to octreotide LAR.

**Methods:** A phase II, open-label, multicenter study of pasireotide was initiated in patients with metastatic NET whose symptoms of carcinoid syndrome were inadequately controlled by octreotide LAR. Patients had histopathologically confirmed metastatic NET, elevated 5-HIAA and/or chromogranin A levels, and at least one measurable lesion (excluding bone). Pasireotide was initiated at 150 µg sc bid, escalated to a maximum of 1200 µg sc bid in patients with suboptimal response. Symptom control on a fixed-dose of pasireotide was defined as: complete (a mean of ≤3 bowel movements [BM]/day, with ≤3 BM on any day, with no flushing episodes) or partial (a mean of <4 BM/day with ≤6 BM on any day, and a mean of <2 flushing episodes/day).

**Results:** Forty-five patients received ≥1 dose of pasireotide and 44 qualified for efficacy assessment. The median treatment duration was 13 weeks (range 0–85). Complete or partial symptom control was achieved by 12 (27%) patients at a dose of 600–900 µg bid; three (7%) patients achieved complete symptom control and nine

patients (20%) experienced partial symptom control. Mean duration of complete or partial symptom control was 43.7 and 72.0 days, respectively. Evaluation of tumor response (RECIST) in 23 patients showed 13 with stable disease and 10 with progressive disease at study end. The most common drug-related adverse events were: nausea (27%), abdominal pain (20%), weight loss (20%), and hyperglycemia (16%).

**Conclusions:** Pasireotide 600–900 µg sc bid was effective and generally well tolerated in controlling symptoms of carcinoid syndrome in 27% of patients with advanced NET refractory or resistant to octreotide LAR therapy.