C31

# Efficacy of Octreotide Long-Acting Repeatable (OCT) From the Phase III RADIANT-2 Study in Patients With Advanced Neuroendocrine Tumors (NET): A Post-Hoc Analysis of the Placebo (PBO) Arm With Updated Survival Data

**Jonathan R. Strosberg**[1]; James C. Yao[2]; Emilio Bajetta[3]; Mounir Aout[4]; Bert Bakker[5*]; John D. Hainsworth[6]; Philippe B. Ruszniewski[7]; Eric Van Cutsem[8]; Kjell E. Öberg[9]; Marianne E. Pavel[10]

[1]Department of Gastrointestinal Oncology, Moffitt Cancer Center, Tampa, FL 33635, United States
Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine
[2]The University of Texas MD Anderson Cancer Center, Houston, TX 77001, United States
[3]Istituto di Oncologia, Policlinico di Monza, Monza, Italy
[4]Novartis Pharma AG, Basel, Switzerland
[5]Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936, United States
[6]Sarah Cannon Research Institute, Nashville, TN 37201, United States
[7]University of Paris VII and Hopital Beaujon, Paris, France
[8]Digestive Oncology Unit, University Hospital Gasthuisberg/Leuven, Leuven, Belgium
[9]Uppsala University Hospital, Uppsala, Sweden
[10]Department of Hepatology and Gastroenterology, Charité-Universitätsmediz in Berlin/Campus Virchow Klinikum, Berlin, Germany
*Current affiliation: Versartis, Menlo Park, CA 94025, United States

**Background:** OCT demonstrated antitumor activity and significantly extended time to tumor progression (TTP) vs PBO in patients with metastatic midgut NET (PROMID trial, Rinke et al. 2009). The RADIANT-2 study evaluated patients with symptomatic advanced NET. Here we report a post-hoc analysis assessing progression free survival (PFS) and overall survival (OS) of OCT (30 mg q28d) in the PBO+OCT arm of this study for the overall population and patients with midgut NET.

**Methods:** Patients eligible for the RADIANT-2 study had progressive disease within the past 12 months and a history of carcinoid symptoms (diarrhea or flushing). PFS (by central review as per RECIST 1.0, cutoff, April 2, 2010) and OS (cutoff, June 13, 2013) in the PBO+OCT arm were estimated by prior somatostatin analogue (SSA) use and primary tumor location subgroups using the Kaplan-Meier method.

**Results:** 213 patients were randomized to PBO+OCT. Of these, 47 (22%) were SSA naive (foregut, 32%; midgut, 51%; hindgut, 4%; not classified or missing, 13%) and 166 (78%) had received SSA (foregut, 10%; midgut, 72%; hindgut, 11%; not classified or missing, 7%) prior to study entry. Median PFS and OS findings are presented in the Table.

**Table. PFS and OS in Patients With and Without Prior SSA in the PBO Arm of RADIANT-2**

| | **No-prior SSA** median (95% CI) | **Prior SSA**[a] median (95% CI) |
|---|---|---|
| PFS (months) | 13.6 (8.2-22.7) (n=47) | 11.1 (8.4-14.2) (n=166) |
| PFS, midgut NET (months) | 22.2 (8.3-29.5) (n=24) | 12.0 (8.4-17.7) (n=119) |
| OS (months) | 50.6 (36.4-NR) (n=47) | 33.0 (24.5-43.7) (n=166) |
| OS, midgut NET (months) | NR[b] (42.4–NR) (n=24) | 33.5 (27.5–49.4) (n=119) |

[a]Includes patients who previously received OCT or lanreotide. [b]For patients with midgut NET who did not receive prior SSA, the OS was not reached (NR) at a median follow-up of 64 months.

**Conclusions:** This post-hoc analysis, for the first time, provides prospective data on survival outcomes of patients with progressive NET treated with SSA therapy. SSA-naive patients with progressive midgut NET treated with OCT had a relatively long median PFS of 22.2 months, exceeding the TTP of 14.3 months observed in the PROMID study (World Health Organization criteria). This data may represent a more accurate reflection of PFS by RECIST associated with first-line SSA use in midgut NET.