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Effect of Open-Label Everolimus in Patients with Advanced Neuroendocrine Tumors After Disease Progression on Somatostatin Analog: A RADIANT-2 Analysis

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Background: In the RADIANT-2 study (NCT00412061), everolimus + octreotide LAR (E+O) resulted in a clinically meaningful increase in median progression-free survival (PFS; by adjudicated central review) of 5.1 months versus placebo + octreotide LAR (P+O) in patients with advanced NET with a history of carcinoid syndrome. Investigator-assessed PFS was 12.0 months for E+O compared with 8.6 months for P+O, respectively. Upon radiological disease progression (as per investigator assessment), P+O patients could cross over to open-label E+O. Here we present the outcomes of P+O patients who crossed over to open-label E+O.

Methods: 429 patients were randomly assigned: 216 to E (10 mg/d) + O (30 mg IM q 28 d) and 213 to P+O.

Results: Upon radiological disease progression per investigator assessment, 124 P+O patients crossed over to open-label E+O. Median duration of treatment with open-label E+O was 26.3 weeks (range, 1-133); 34 patients (27.4%) received open-label E+O for ≥12 months. Median time from randomization to crossover to open-label E+O was 14.1 months. Median PFS in the open-label E+O group, calculated from time of crossover and assessed by local investigators, was 10.1 months (95% CI, 8.0-13.5). Adverse events were similar to those reported for the E+O arm during the double-blind phase of the study.

Conclusions: Patients with NET enrolled in the RADIANT-2 study who received open-label E+O after progressing on P+O had median PFS of 10.1 months with no unexpected adverse events.

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