Everbolimus (n/N = 109/207) Placebo: (n/N = 94/203)

Impact of Previous Chemotherapy on Progression-Free Survival in Patients With Advanced Pancreatic Neuroendocrine Tumors: Results From the RADIANT-3 Trial
Rudolf Pommer,1 Edward Wolin,2 Ashok Parikhlesar,3 Stephen Saltz,4 Robert E. Winkler,5 Eric Van Cutsem6
1Oregon Health & Science University, Portland, Oregon, 2 Cedars-Sinai Medical Center, Los Angeles, California, 3 Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, 4 University Hospital Gasthuisberg-Leuven, Leuven, Belgium

BACKGROUND
- Pancreatic neuroendocrine tumors (pNET) are rare neoplasms that account for <5% of incident solid tumors and are included in <10% of incident neuroendocrine tumor (NET) clinical trials.
- In approximately 65% of patients with pNET, the disease is not diagnosed until it is advanced, with a median survival time for patients of 2 months.
- Until recently, the only US Food and Drug Administration-approved treatment option for patients with pNET was somatostatin analogs, though its usefulness in advanced pNET is unclear.

OBJECTIVE
- To perform an exploratory analysis of the effect of everolimus on PFS in patients with and without previous chemotherapy.
- To determine the role of previous chemotherapy in the treatment of pNET.

METHODS
Study Design and Patient Population
- The trial was an international, multicenter, double-blind, placebo-controlled, phase III RADIANT-3 trial involving 410 patients with progressive or metastatic, non–resectable, locally advanced, or metastatic pNET.
- Patients were stratified by previous or no previous chemotherapy.

RESULTS
- Everolimus significantly increased median PFS 2.4-fold versus placebo (11.0 months vs 4.6 months; P < 0.001) and similar to that observed in the overall population (8.15-13.87).
- Median follow-up in the overall population was 17 months; median exposure was 37.8 weeks with everolimus and 28.4 weeks with placebo.

CONCLUSIONS
- Everolimus compared with placebo associated with statistically significant improvement in PFS among patients who received previous chemotherapy and by 4.6 months in patients who received no previous chemotherapy compared with placebo.
- Median follow-up in the overall population was 17 months; median exposure was 37.8 weeks with everolimus and 28.4 weeks with placebo.

REFERENCE