Impact of Prior Chemotherapy (Chemo) on Progression-free Survival (PFS) in Patients (Pts) with Advanced, Nonfunctional Lung or Gastrointestinal (GI) Neuroendocrine Tumors (NET): A Secondary Analysis from the Phase 3 RADIANT-4 Study

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Background: In the phase 3 RADIANT-4 study, everolimus (EVE) improved PFS by 7.1 months (mo) compared to placebo (PBO; P<0.00001) in pts with advanced, progressive, nonfunctional NET of lung or GI tract. This sub group analysis evaluated impact of prior chemo use on PFS in RADIANT-4.

Methods: In RADIANT-4, pts were randomized (2:1) to EVE 10mg/d or PBO, both with best supportive care. A subgroup analysis of the RADIANT-4 study by prior chemo use is presented.

Results: Of 302 pts, 77 (25%) had received chemo (EVE, n=54 & PBO, n=23) and 225 (75%) were chemo-naïve (EVE, n=151 & PBO, n=74) prior to study entry. Baseline characteristics were comparable between subgroups. Primary tumor sites (prior chemo vs chemo-naïve): Lung (49% vs 23%), GI (38% vs 65%), NET of unknown primary (13% vs 12%). Median PFS (95%CI) in prior chemo group (EVE vs PBO) was 9.2 (5.6-11.7) mo vs 2.1 (1.9-3.7) mo (HR 0.35; 95%CI 0.19-0.64). In chemo-naïve group (EVE vs PBO), median PFS (95%CI) was 11.2 (9.2-16.6) mo vs 5.4 (3.7-9.0) mo (HR 0.60; 95%CI 0.42-0.86). Most frequent drug-related G3/4 AEs (EVE vs PBO) in prior chemo group: stomatitis (9% vs 0), anemia (8% vs 4%) & diarrhea (6% vs 0); chemo-naïve group: diarrhea (8% vs 3%) & stomatitis (7% vs 0).

Conclusion: EVE improved PFS in pts with advanced, well-differentiated, progressive, nonfunctional NET of lung or GI origin irrespective of prior chemo use. EVE safety profile was similar to overall RADIANT-4 population.

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