Association of Disease Progression, Health-related Quality of Life (HRQoL), and Utility in Patients with Advanced, Nonfunctional, Well-differentiated Gastrointestinal (GI) or Lung Neuroendocrine Tumors (NET) in the Phase 3 RADIANT-4 Trial

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Background: Post hoc analyses were performed to determine if disease progression is associated with decline in HRQoL and utility scores using data from RADIANT-4, a phase 3 trial that showed significantly prolonged progression-free survival (PFS) with everolimus + best supportive care (BSC) vs placebo + BSC.

Methods: Pooling data from both arms, 284 patients were analyzed. HRQoL was measured with FACT-G, a validated questionnaire with 4 domains: physical (PWB), social/family (SWB), emotional (EWB), and functional wellbeing (FWB). FACT-G was completed at baseline, every 8 weeks until month 12 after randomization, and every 12 weeks thereafter. Association between disease progression and HRQoL was assessed by fitting linear mixed models. Based on a review of existing mapping functions, 2 mapping algorithms were selected to translate FACT-G scores into EQ-5D utility scores: Young, Med Decis Making 2015 (UK value set); Teckle, Health Qual Life Outcomes 2013 (US value set).

Results: The difference in FACT-G total score pre- vs post progression was significant: 79.7 vs 74.8 (difference: 4.91; 95% CI: 3.71, 6.11) and may be clinically relevant based on published ranges for minimal important difference (Yost & Eton, Eval Health Prof 2005). Differences in subscale scores were: PWB 22.4 vs 20.9 (1.5; 95% CI: 1.05, 1.95); EWB 17.6 vs 16.4 (1.14; 95% CI: 0.78, 1.49); SWB 21.6 vs 20.9 (0.69; 95% CI: 0.24, 1.14); and FWB 18.2 vs 16.9 (1.34; 95% CI: 0.86, 1.82).

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Mean "Teckle" utility was 0.826 (95% CI: 0.815, 0.836) pre-progression and 0.795 (95% CI: 0.783, 0.807) post-progression; mean "Young" utility was 0.779 (95% CI: 0.763, 0.796) pre-progression and 0.725 (95% CI: 0.706, 0.744) post-progression.

Conclusion: Disease progression in patients with advanced, nonfunctional, well-differentiated GI or lung NET is associated with a significant decline in HRQoL and utility scores. Effective therapy to prolong PFS may delay a decline in HRQoL and utility.