INTRODUCTION

Sunitinib is an oral, multitargeted tyrosine kinase inhibitor approved for use in advanced renal cell carcinoma and gastrointestinal stromal tumors. Activity against pancreatic neuroendocrine tumors (NET) has been demonstrated in preclinical and phase I and II trials.1

In Europe (sunitinib; a double-blind trial NCT00482959) in patients with well-differentiated, advanced, progressive pancreatic NET, median progression-free survival (PFS) was significantly prolonged with sunitinib (n=88), compared with placebo (n=85): 11.4 months (95% confidence interval [CI] 7.4, 19.8) vs. 5.5 months (95% CI 3.6, 7.4), respectively (P=0.018, HR 0.41, 95% CI 0.26, 0.66; P=0.001).

The HR for overall survival was 0.409 favoring sunitinib (95% CI 0.187, 0.894; P=0.022).

Sunitinib was generally well tolerated, with most adverse events manageable by dose interruption, dose reduction, and/or standard medical therapy.2

Here we present exploratory subgroup analyses, evaluating the impact of baseline characteristics on treatment response and patient-reported outcomes (PROs).

METHODS

• Patients with well-differentiated advanced pancreatic NET and disease progression in the past 12 months were randomized (1:1) to once-daily treatment with or without 375 mg sunitinib, continuously daily or on a 4-week on, 2-week off schedule, or matching placebo, each with best supportive care. Treatment was continued until Response Evaluation Criteria in Solid Tumors-defined progression, unacceptable adverse events, or death.

• Somatostatin analogs (SSAs) were allowed before and/or during the study.

• Ki-67 index

• Prior systemic treatment, n (%)

• Gender, n (%)

• Use of SSAs prior to or during the study vs. no use

• Ki-67 index

• Global health status/QoL, functioning (physical, role, cognitive, emotional, social)

• ECOG PS

• Placebo

• Prior treatments, n (%)

• Other/unspecified*

• Grade of adverse event

• Use of SSAs at any time before and/or concomitant with study treatment

• Global health status

• Other/unspecified*

• Asian

• Treatment-related death

• Other/unspecified*

• ≤2 disease sites†

• Region of the world

• ≥3 sites†

• Other/unclassified

• Age

• Placebo

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