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Final phase II results for sunitinib (SU) in Japanese pts with well-differentiated pancreatic neuroendocrine tumor (NET)

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Background: SU is an oral, multikinase inhibitor effective in pts with unresectable, well-differentiated pancreatic NET. Final results from an open-label, phase II trial of SU in Japanese pts with this disease are reported.

Methods: Pts received SU 37.5 mg/d continuous daily dosing (CDD). The primary endpoint was clinical benefit rate (CBR; complete response [CR] + partial response [PR] + stable disease [SD] ≥ 24 wk). Secondary endpoints included: objective response rate (ORR; CR + PR), progression-free survival (PFS), overall survival (OS; assessed up to 3 y after enrollment was completed or until the median was reached), safety and pharmacokinetics. Tumor assessments were performed at baseline and 8-wk intervals by CT or MRI (RECIST).

Results: From Jul to Dec 2010, 12 pts enrolled (median age 54 y, range 34-79) and, by Jan 2013, all had completed treatment (median treatment duration 14 mo). CBR was 75% (95% CI: 43-95); 6 had PR and 3 had SD ≥ 24 wk. ORR was 50% (95% CI: 21-79). Median PFS was 16.8 mo (95% CI: 9.3-26.2). At the final OS cutoff (Nov 2013; 3 y after last pt, first visit), median OS could not be estimated due to an insufficient number of events. The OS rate at 12 and 36 mo was 90.9% and 54.5%, respectively. One pt discontinued due to AEs. The most common all-causality any-grade (G) AEs were diarrhea (n = 10, 83%), hand-foot syndrome and hypertension (both n = 8, 67%), and headache and fatigue (both n = 7, 58%). G3 AEs reported in ≥ 2 pts were neutropenia (n = 6, 50%) and leukopenia (n = 2, 17%). G4 AEs were observed in 4 pts: increased lipase (n = 2) and convulsion, loss of consciousness, herpes encephalitis and enterocolitis (all n = 1). Optimal long-term management of SU-related AEs and exploratory subgroup analyses of AE incidence, dose reduction/interruption and trough concentrations by SU treatment duration will be reported.

Conclusion: SU had antitumor activity in Japanese pts with well-differentiated pancreatic NET. Common AEs were as expected with SU.