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Poster Session One...Late Breaking Abstracts

Safety and efficacy of second-line sunitinib in gastrointestinal stromal tumour patients in a worldwide treatment-use trial

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Abstract No. LB31

Safety and efficacy of second-line sunitinib in gastrointestinal stromal tumour patients in a worldwide treatment-use trial

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Sunitinib malate (SU) is an oral, multitargeted tyrosine kinase inhibitor approved for the treatment of imatinib (IM)-resistant/-intolerant gastrointestinal stromal tumour (GIST). This ongoing, open-label trial provides SU to a broad population of GIST patients ineligible for SU clinical trials. Patients with advanced GIST resistant or intolerant to IM received SU 50 mg/day in six-week cycles (four weeks on treatment, two weeks off). As of April 2007, 1022 patients had been enrolled in 96 centres in 33 countries. Patients received a median of 4 cycles (range 1–18) with 195 days follow-up. In patients who received ≥ 1 SU dose (intent-to-treat population; N=1012), dose reductions and discontinuations due to AEs or lack of efficacy occurred in 33%, 15% and 29%, respectively. Fatigue (46%), diarrhoea (42%) and nausea (33%) were the most common AEs of any cause. The most common grade 3/4 AEs were fatigue (9%), hand-foot syndrome (8%) and abdominal pain (8%). Haematologic AEs (total, grade 3/4) included anaemia (19%, 7.4%), thrombocytopenia (16%, 4.5%) and neutropenia (15%, 5.8%). At cut-off, 715 (71%) patients were alive. Estimated median overall survival (OS) was 68.0 wks (95% CI: 60.3–NA) and estimated median time-to-progression was 36 weeks (95% CI: 35–42). Data for subgroups will be presented. SU is generally well tolerated in patients with IM-resistant/-intolerant GIST ineligible for other SU trials. The tolerability of SU is similar to that reported in previous registrational trials. Consistent with previous studies, SU is an effective treatment for patients with advanced GIST after IM failure.

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INSTRUCTIONS

Supported by an educational grant from sanofi-aventis.
 Date of preparation: September 2007. Job number: TAX-07-194.

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